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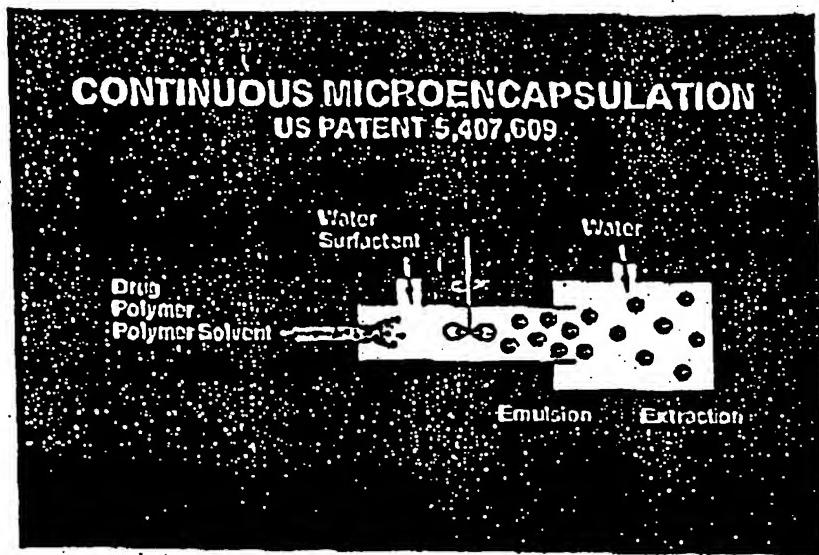
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SOUTHERN RESEARCH'S PATENTED MICROENCAPSULATION PROCESS



Advantages

- US Patent issued 1995
- Fast encapsulation time -- milliseconds
- Minimal exposure to polymer solvent
- High encapsulation efficiency
- Good Yields
- Makes small microparticles
 <100 micron <10 micron

Drugs Microencapsulated

- Proteins
- Peptides
- Small molecules
- Water-soluble drugs
- Hydrophobic drugs
- Drugs encapsulated in
 lactide/glycolide polymers

FIGURE 1

FIGURE 2.

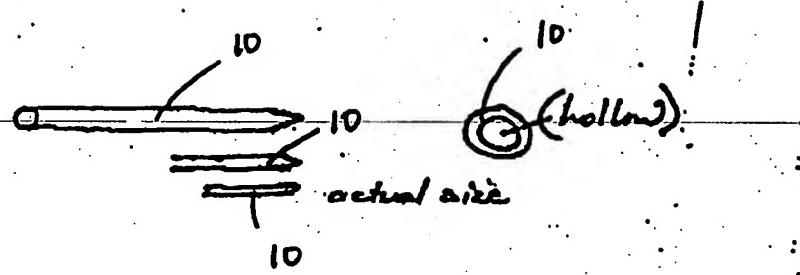


FIGURE 3

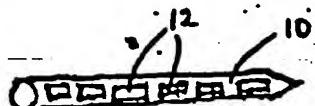
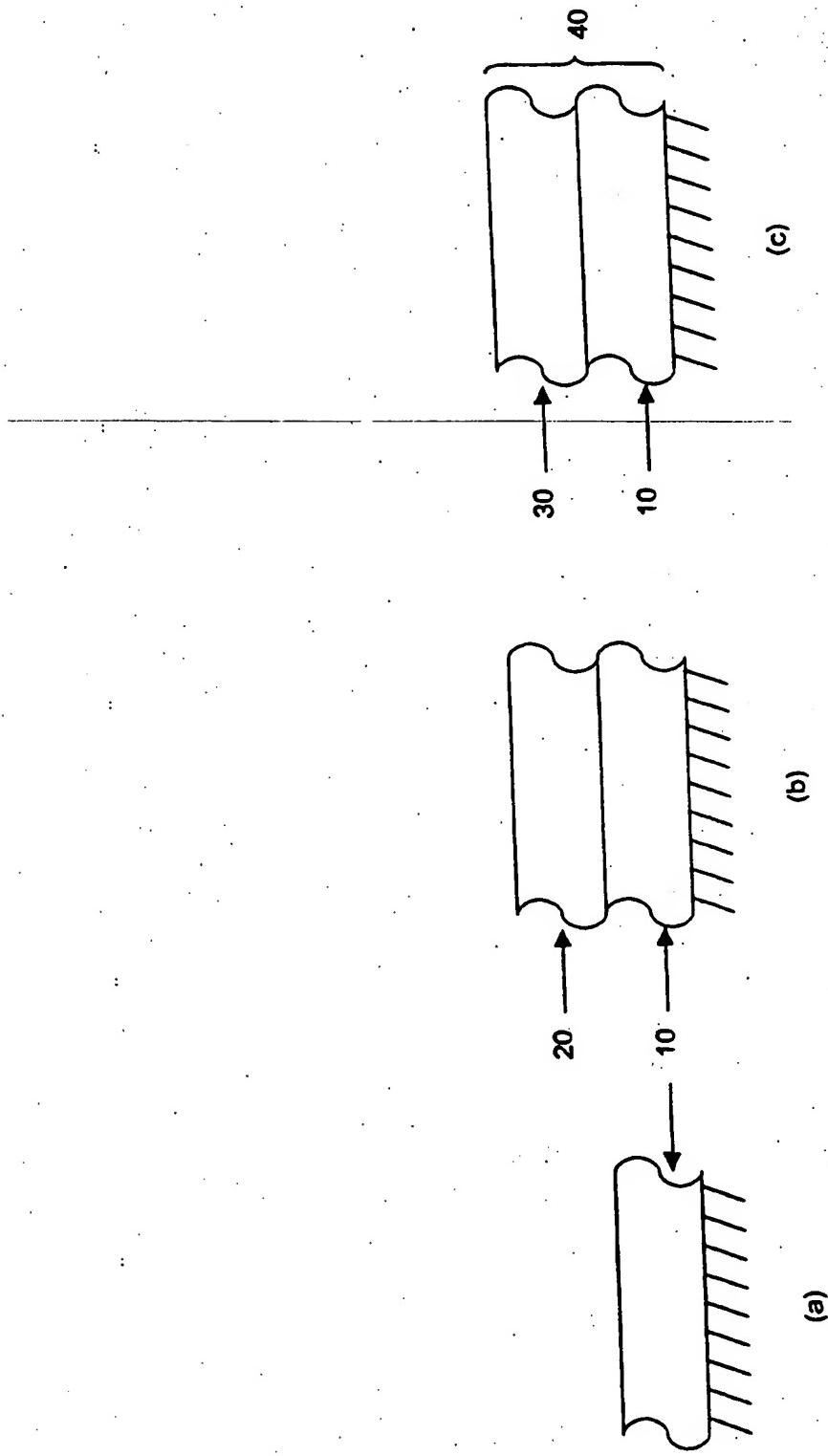


FIGURE 4



Conditions: Ambient

Material:	PX510	PX261	PX749	PX125	PX510 + 14% Paclitaxel
Hardness:	F	B	3B	4B	F

Conditions: 5 minutes in 37°C pH 7.4 Saline Buffer

Material:	PX510	PX261	PX749	PX125	PX510 + 14% Paclitaxel
Hardness:	F	B	9B	<9B	F

Hardness Rating:
2H-H-F-HB-B-2B-3B-4B-5B-6B-7B-8B-9B



FIGURE 5

Conditions: Ambient

Material:	PX510	PX261	PX749	PX125	PX510 + 14% Paclitaxel
Resistance To Cracking	< 3 mm				

Conditions: 5 minutes in 37°C pH 7.4 Saline Buffer

Material:	PX510	PX261	PX749	PX125	PX510 + 14% Paclitaxel
Resistance To Cracking	< 3 mm				

FIGURE 6

Conditions: Ambient

		PX510 + 14% Paclitaxel		
Material:	PX510	PX261	PX749	PX125
Class:	5B	5B	5B	4B

Class Rating: 5B = 0% of coating removed from substrate
4B = Less than 5% of coating removed from substrate

FIGURE 7

FIGURE 8A

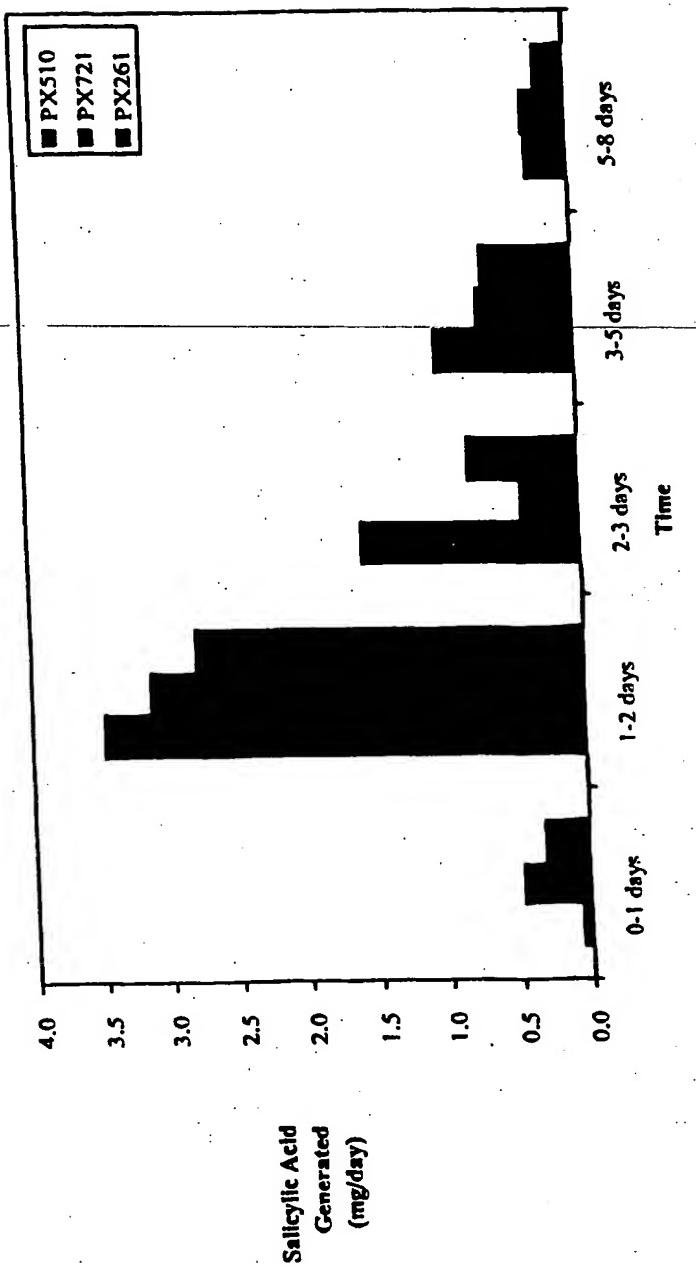


FIGURE 8B

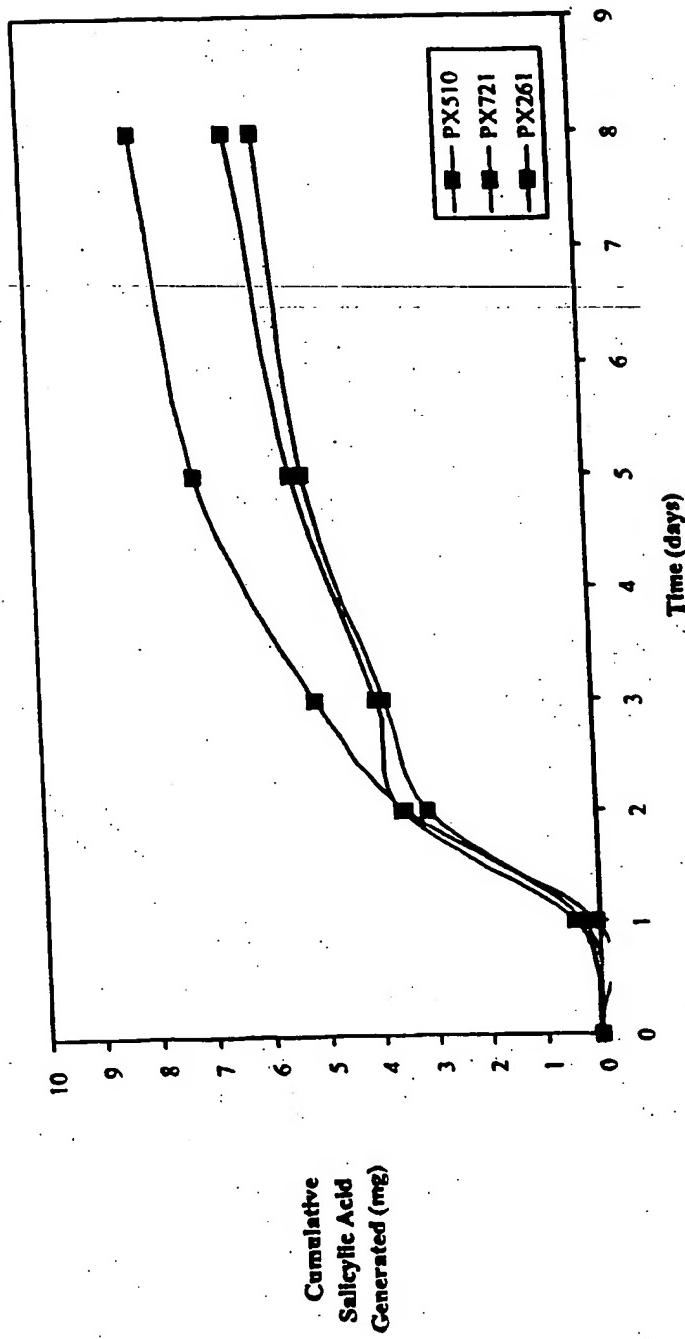
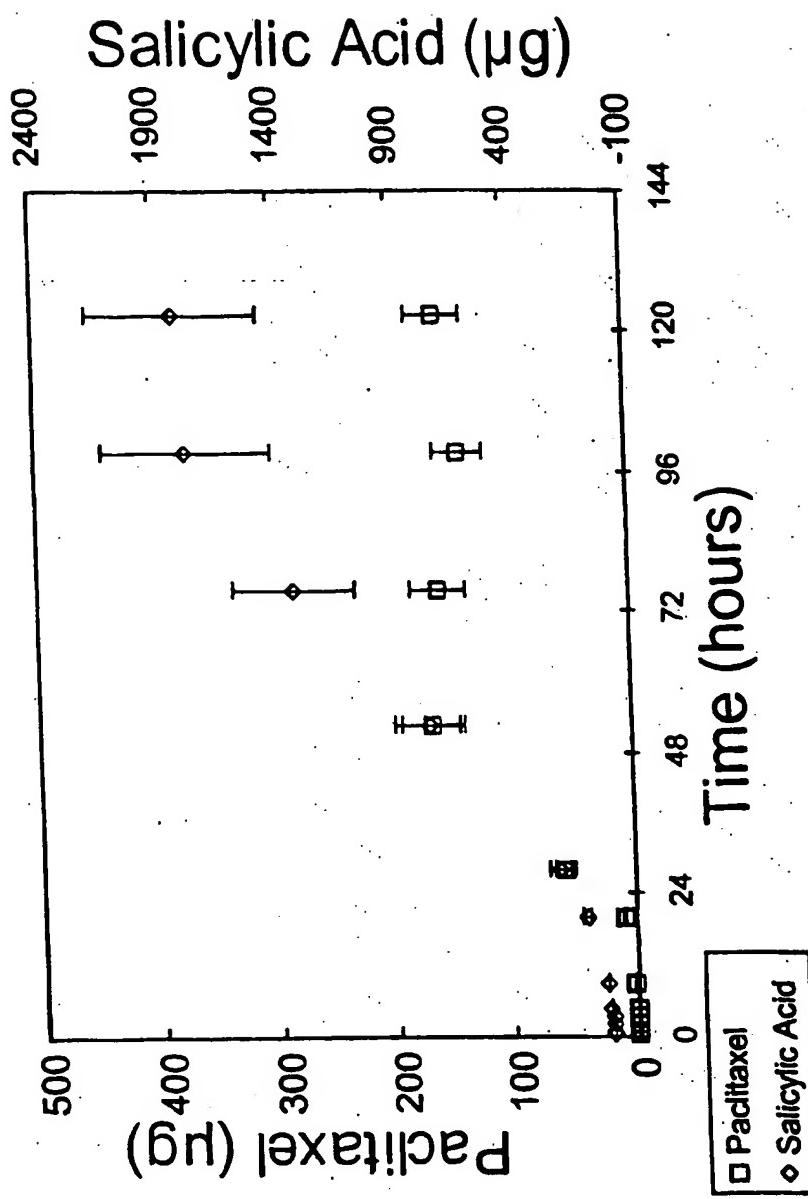


FIGURE 9A



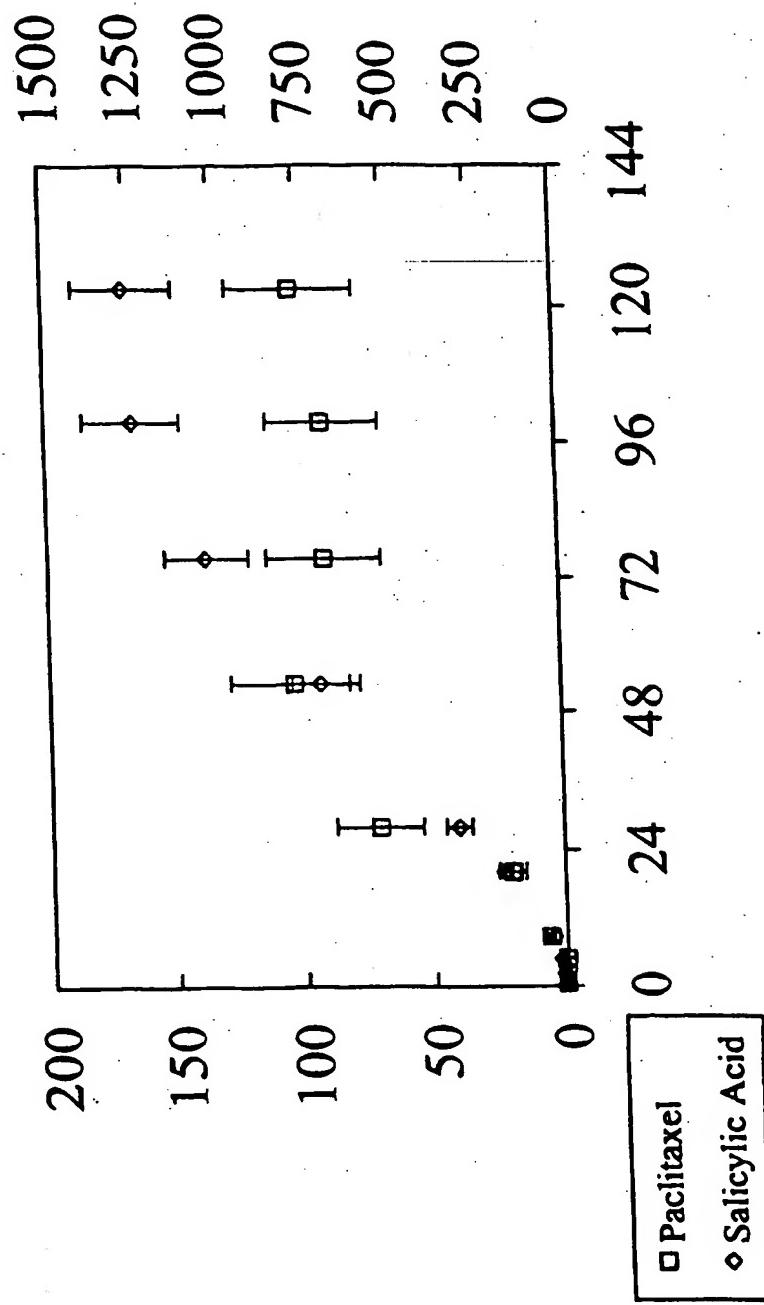


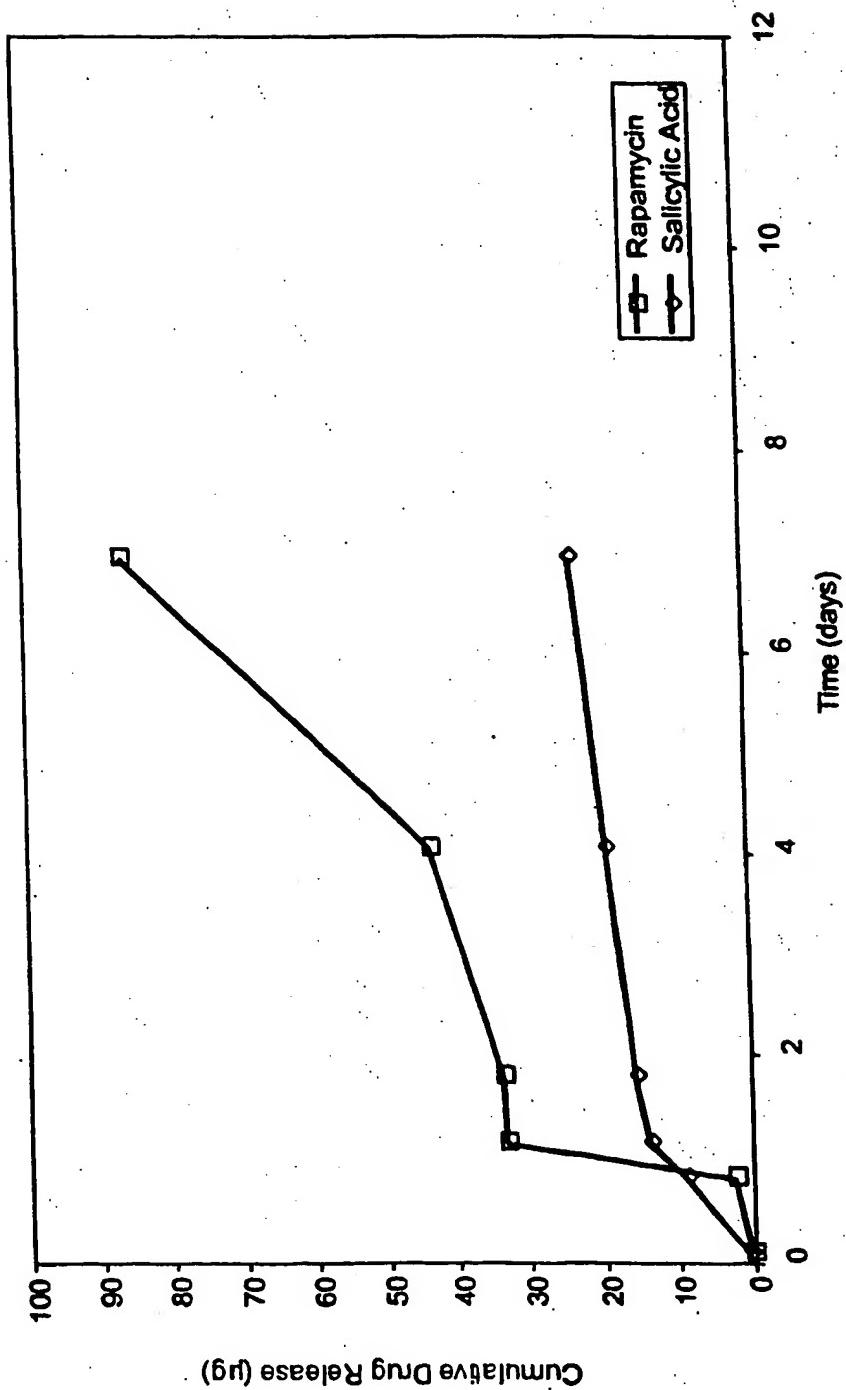
FIGURE 9B

Formulation

Property	PX510	PX721	PX261	PX749
T _g (C)	44	38	29	16
Tensile modulus (MPa)	2.0 (25 C) 5.1 (37 C)			
Yield Strength (MPa)		Not observed		6.0 (25 C)
Ultimate Elongation (%)	1.5 (25 C) 350 (37 C)			500 (25 C)

FIGURE 10

FIGURE 11



	E Beam (3 MRad)		γ (25-35 KGyS)			
Property	PX510	PX721	PX261	PX510	PX721	PX261
MW	-28%	-39%	-26%	-14%	N/C	N/C
Hardness	-2 units	N/C	-1 unit	N/C	-3 units	-2 units
Flexibility	N/C	N/C	N/C	N/C	N/C	N/C
Adhesion	N/C	N/C	-1 unit	N/C	N/C	N/C

N/C: no change

FIGURE 12

FIGURE 13A

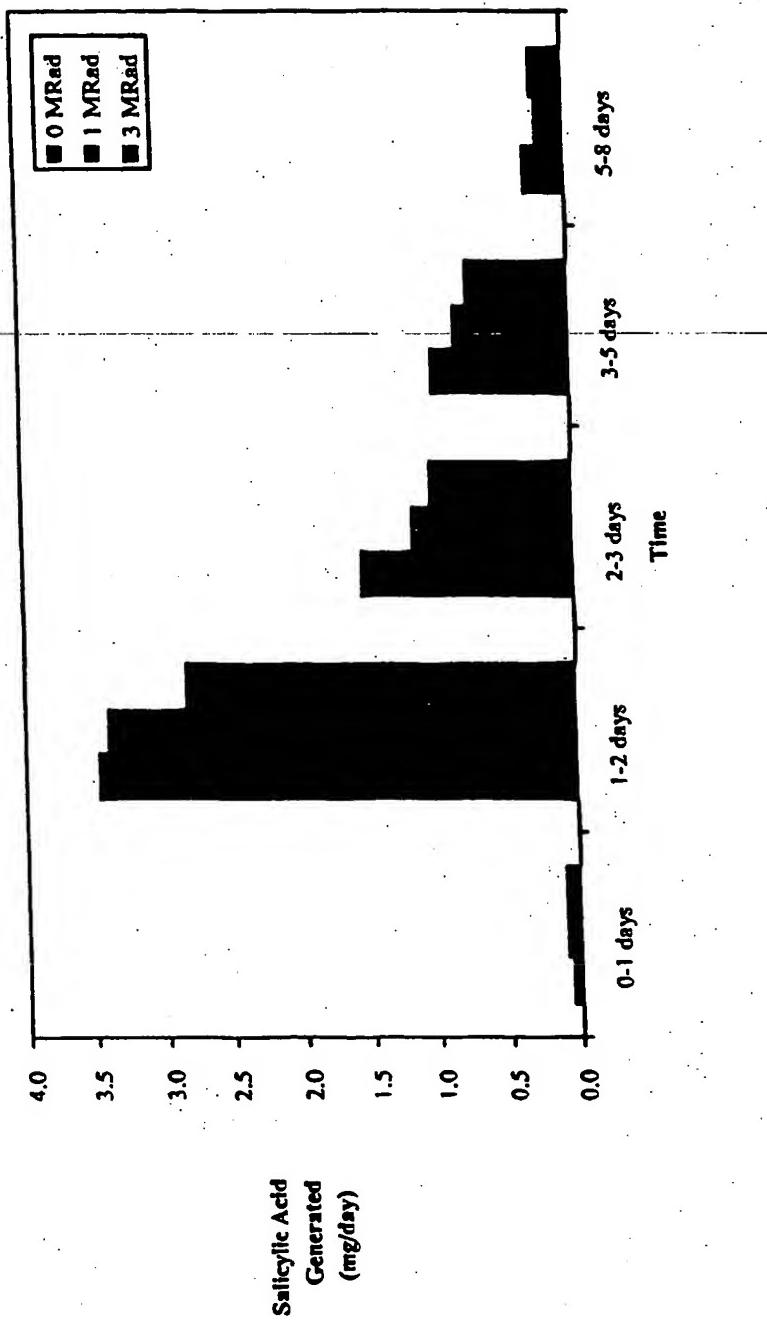
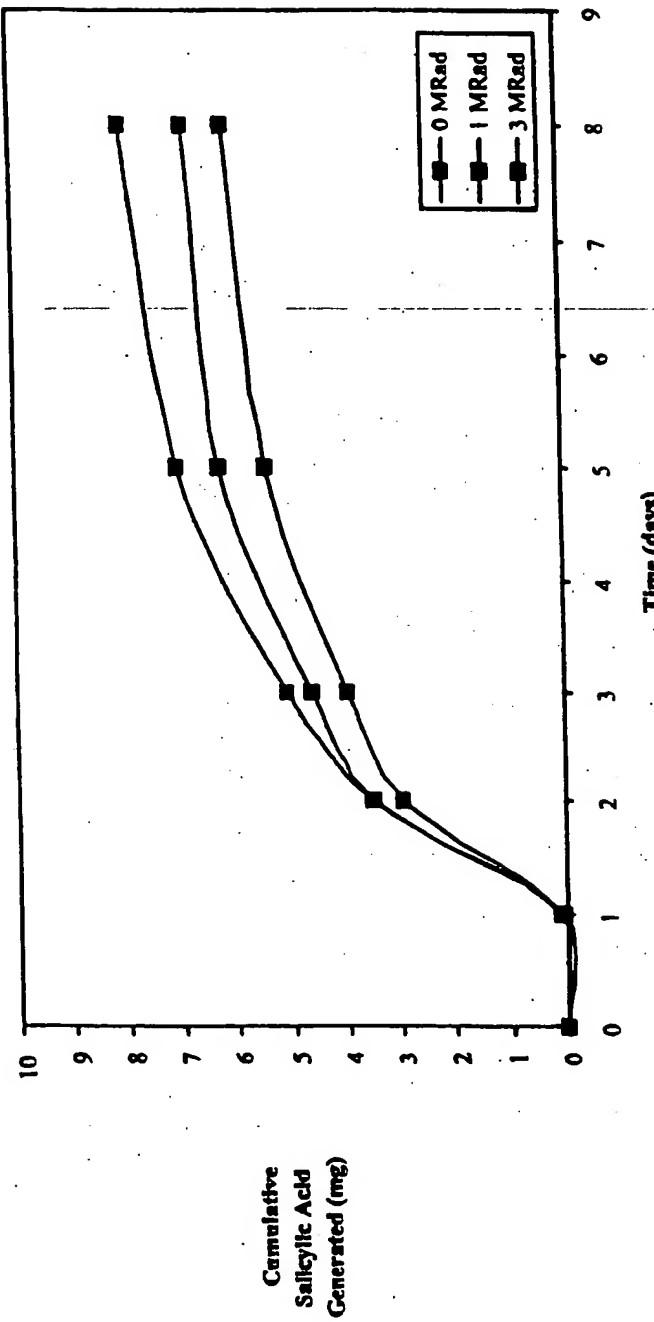


FIGURE 13B



PX242 20-53 Coated Coupon Diflunisal Elution

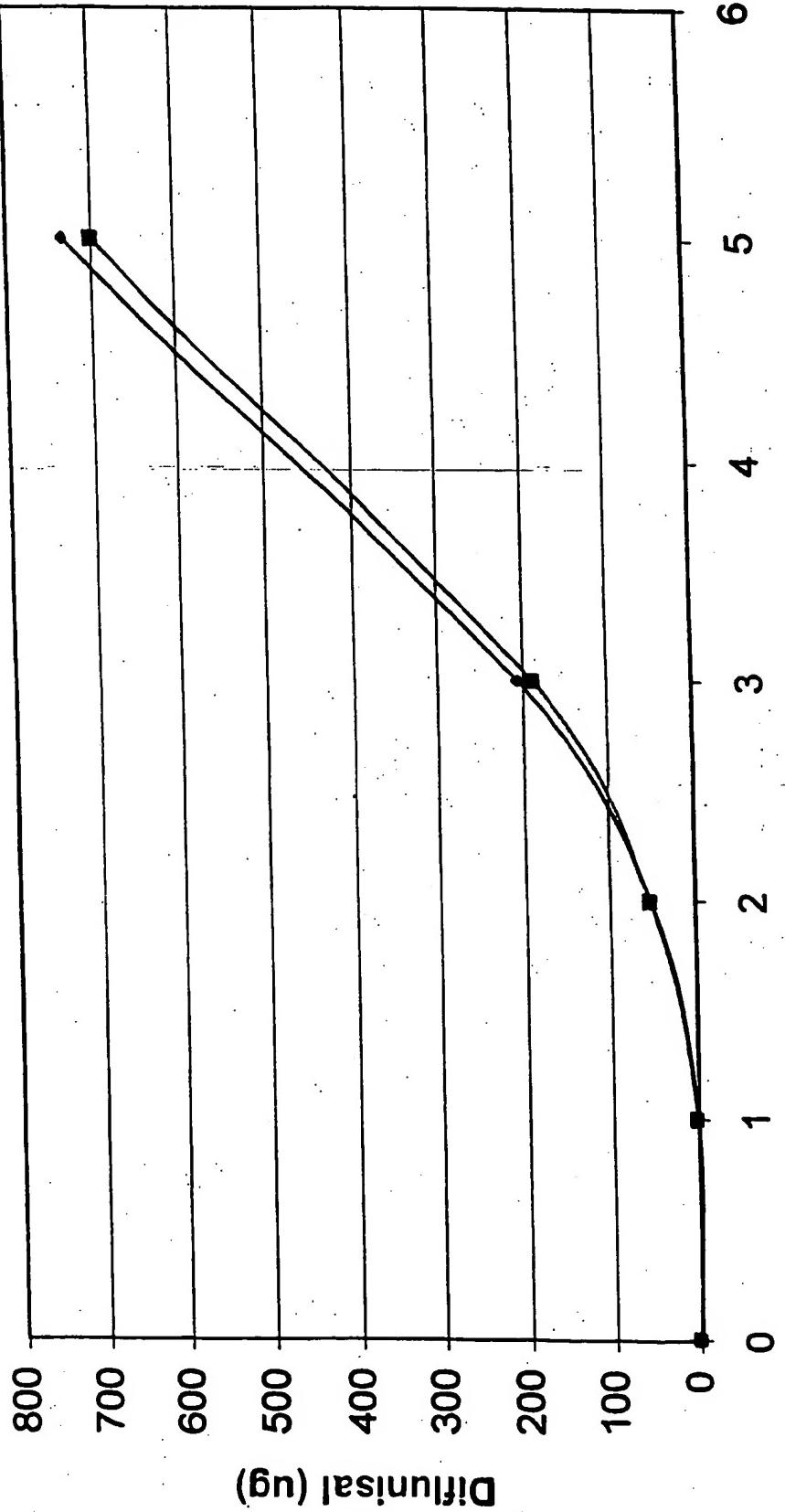


FIGURE 14

PX242 20-53 Coated Coupon Diflunisal Elution

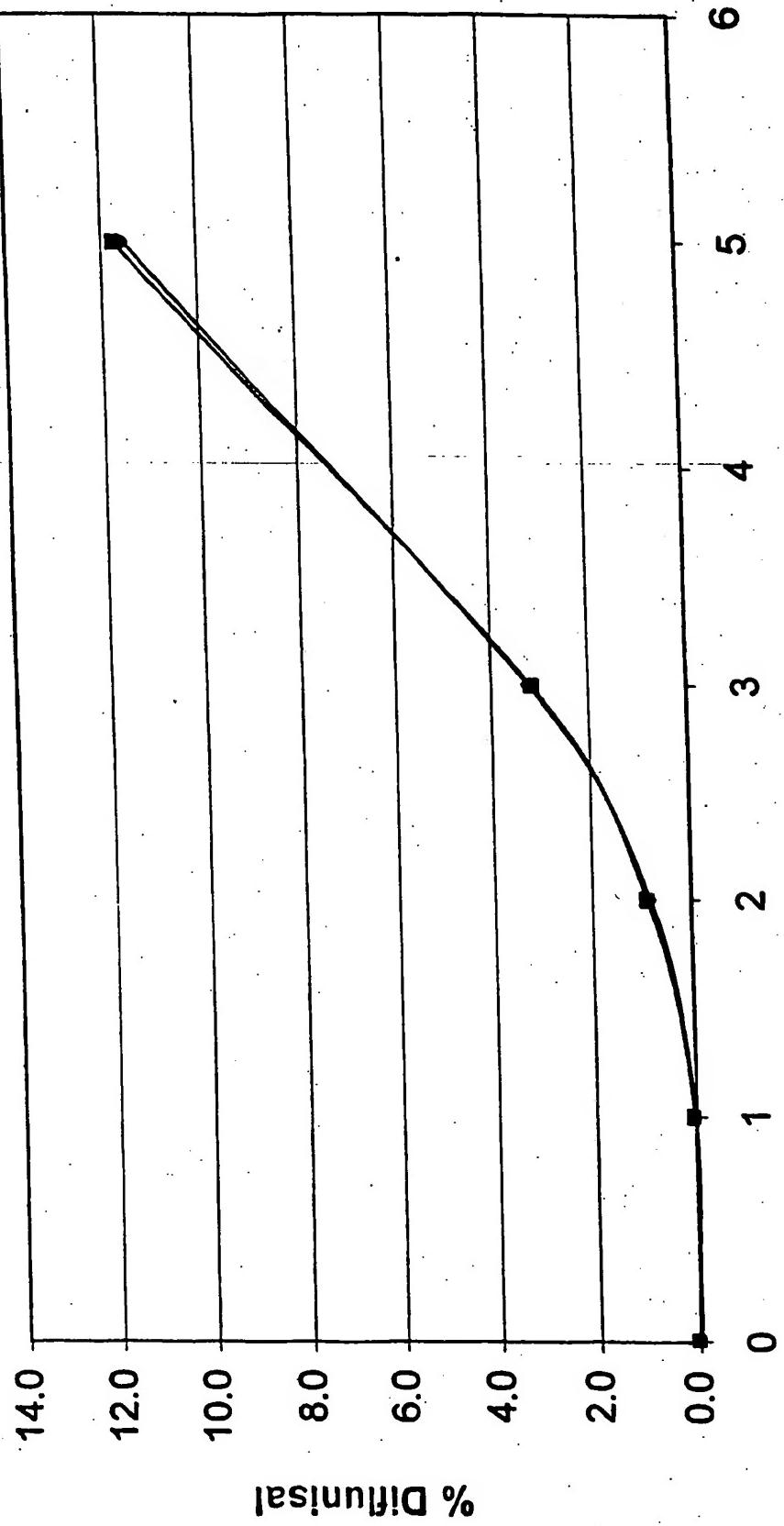
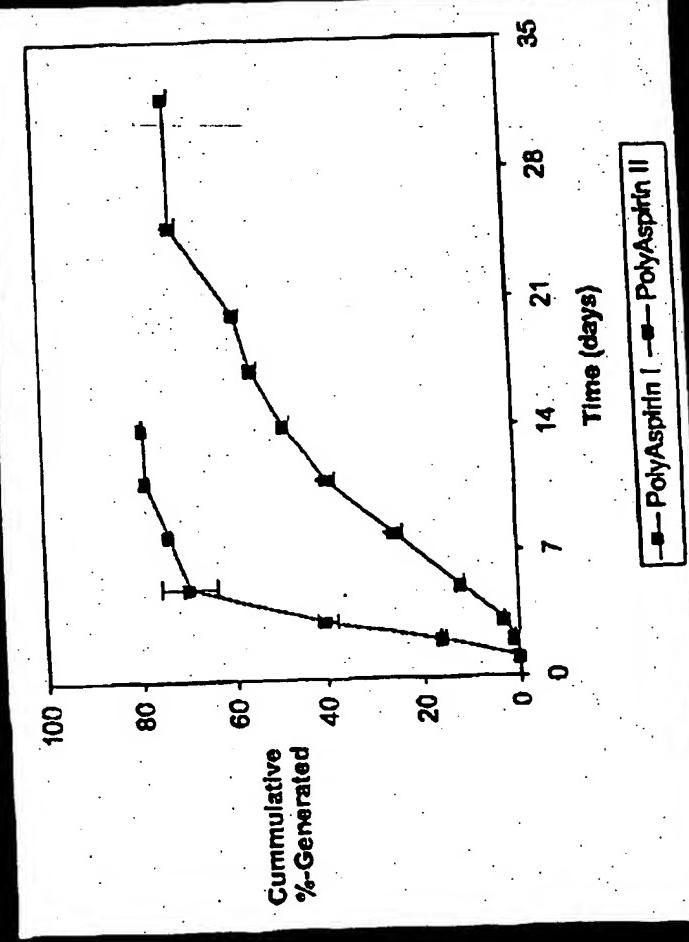


FIGURE 15

Erosion Of PolyAspirin I & II

Generation of NSAID into 37 °C pH 7.4 PBS from ~5 μm-thick Coatings on 316L SS Plates



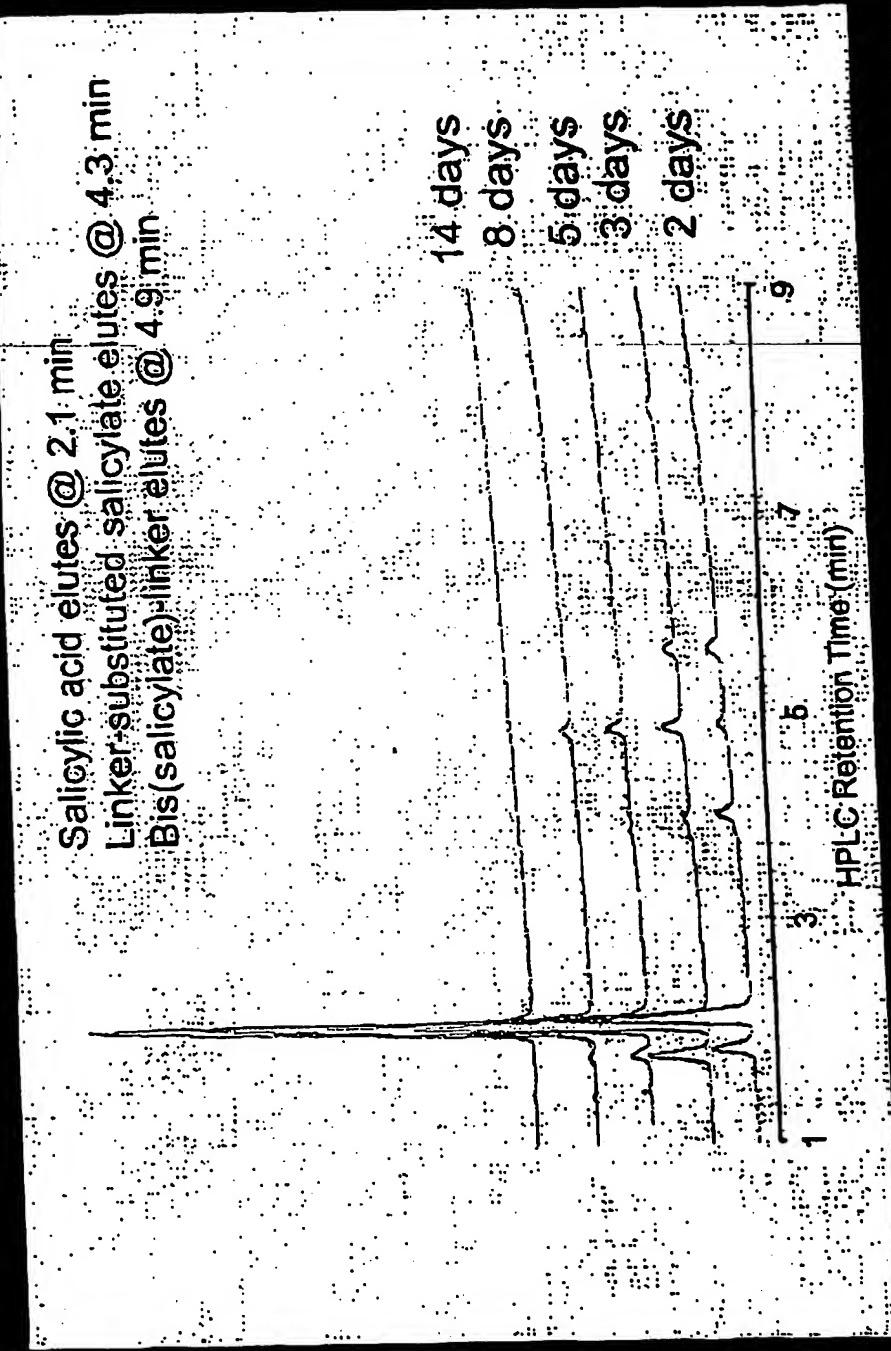
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FIG. 16

Erosion Profile for PolyAspirin I

Salicylic acid elutes @ 2.1 min
Linker-substituted salicylate elutes @ 4.3 min
Bis(salicylate)linker elutes @ 4.9 min

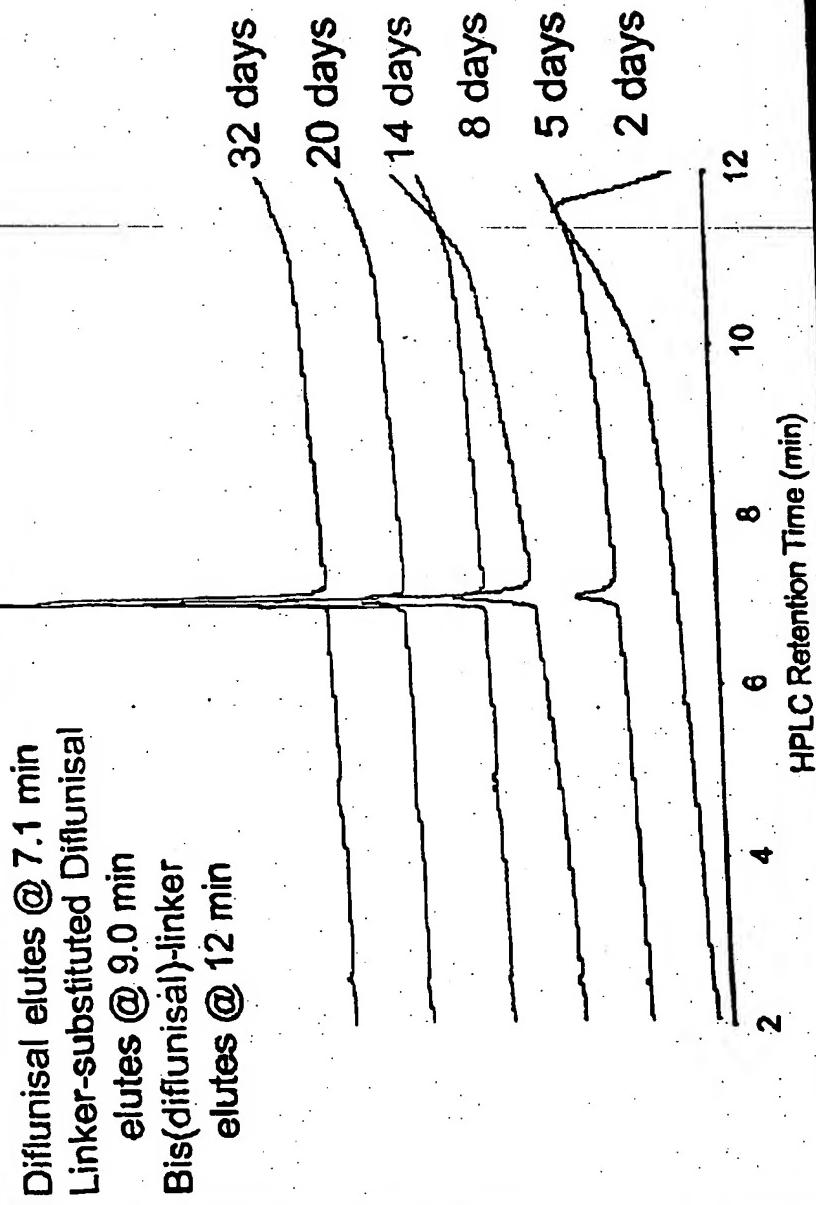


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FIG. 17

Erosion Profile for PolyAspirin II



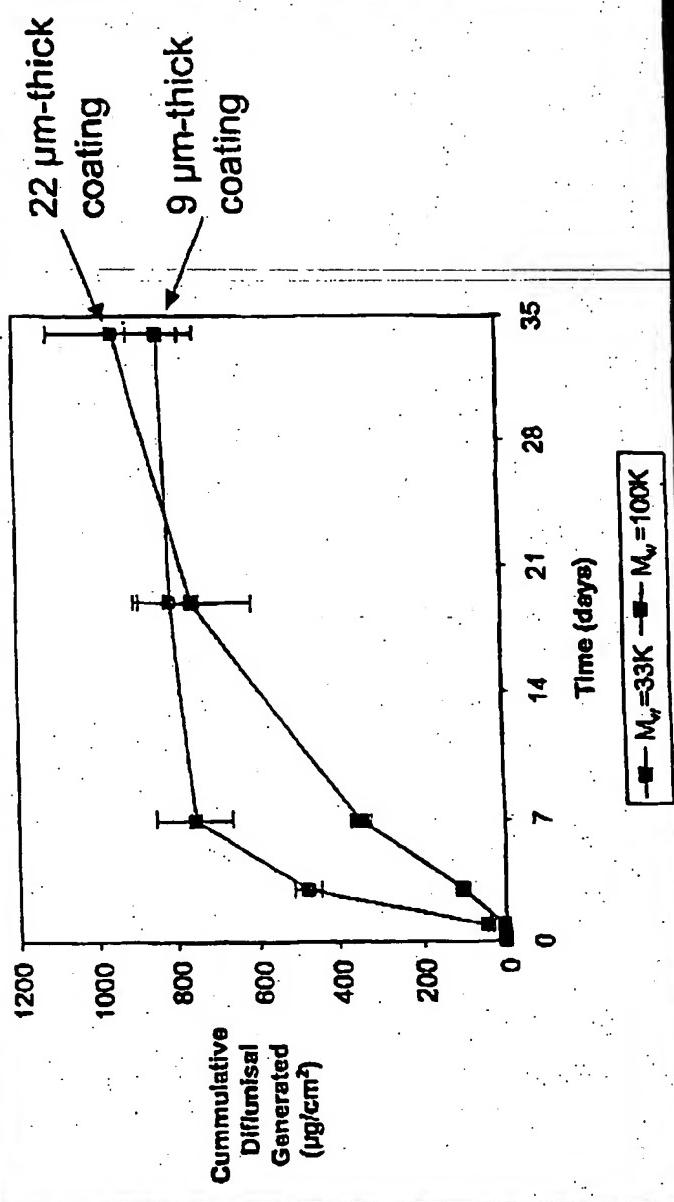
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FIG. 18

Effect Of MW On Erosion

Generation of Diflunisal from PolyAspirin II into 37 °C Serum from Coatings on 316L SS Plates

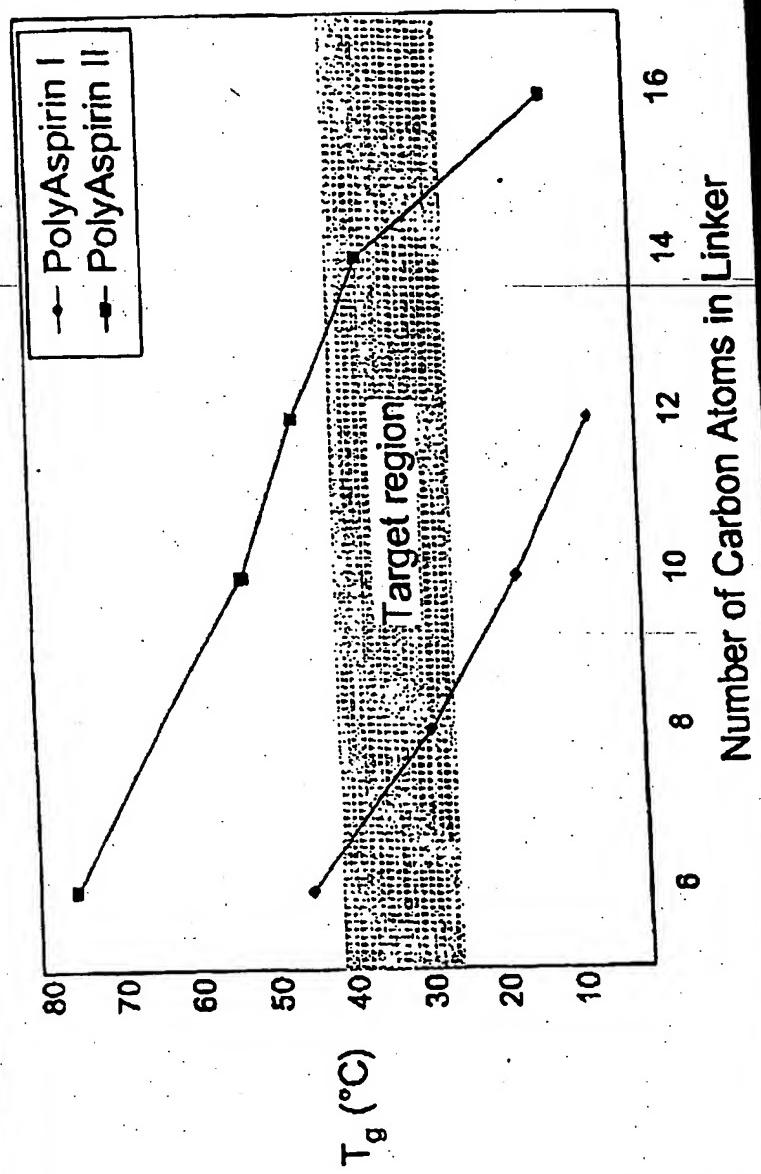


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FIG. 19

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Tuning Mechanical Properties



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FIG. 20

Thermoanalysis of PolyAspirin™

Property	PolyAspirin I	PolyAspirin II
M_w ~ 20K	M_w ~ 33K	M_w ~ 100K
T_g (°C)	29	36
Ultimate Stress (kPa)	>2000 (25°C) >2000 (37°C)	>2800 (25°C)
Ultimate Elongation (%)	>500 (25°C) >500 (37°C)	>4 (25°C)
Toughness (kPa)	>3900 (25°C) >4400 (37°C)	>560 (25°C)
		>4000 (25°C)

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FIG. 21

Properties of PolyAspirin™ Coatings

	PolyAspirin I	PolyAspirin II
Test	PX261 $M_w \sim 20K$	PX657 $M_w \sim 32K$ $M_v \sim 100K$
Hardness	B B .	F 2B 8B
Flexibility	<3 mm <3 mm .	<3 mm <3 mm .
Adhesion	5B	5B

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FIG. 22

PolyAspirin Coatings With Admixtures

PolyAspirin II (PX657)
No Admixture 20% Facitaxel Admixed

Test

Hardness

Ambient

5 min in PBS, 37 °C
1 hr in PBS, 37 °C

F
F
2B
8B

Flexibility

Ambient

5 min in PBS, 37 °C
1 hr in PBS, 37 °C

<3 mm
<3 mm
<3 mm

Adhesion

Ambient

5B

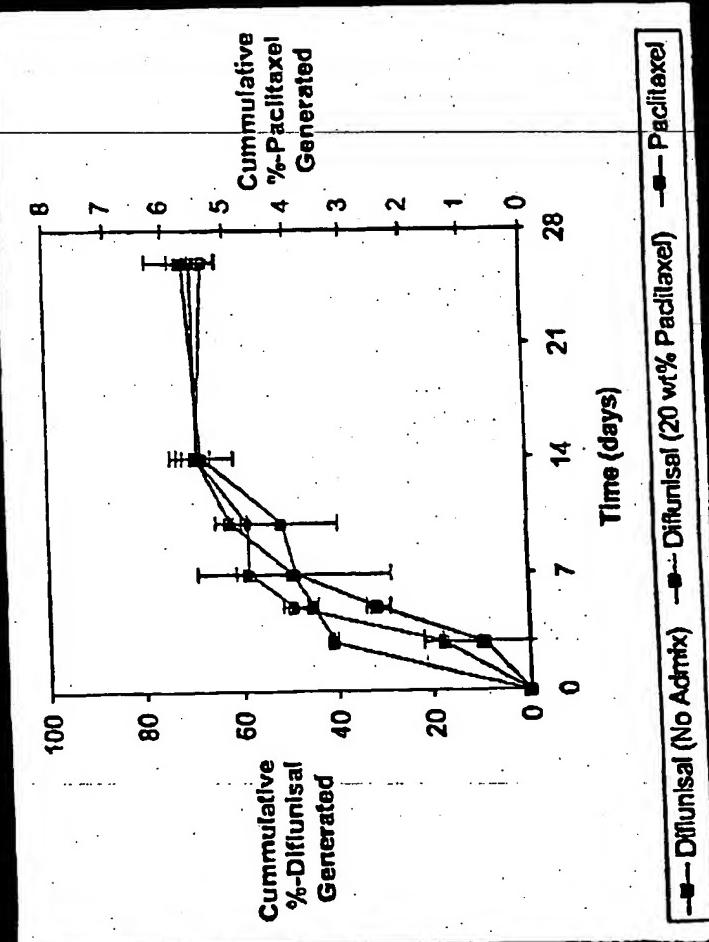
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Information

FIG. 23

Erosion of PolyAspirin I & II

Diflunisal Generation & Paclitaxel Release into 37 °C Serum from ~5 μm-thick Coatings on 316L SS Plates



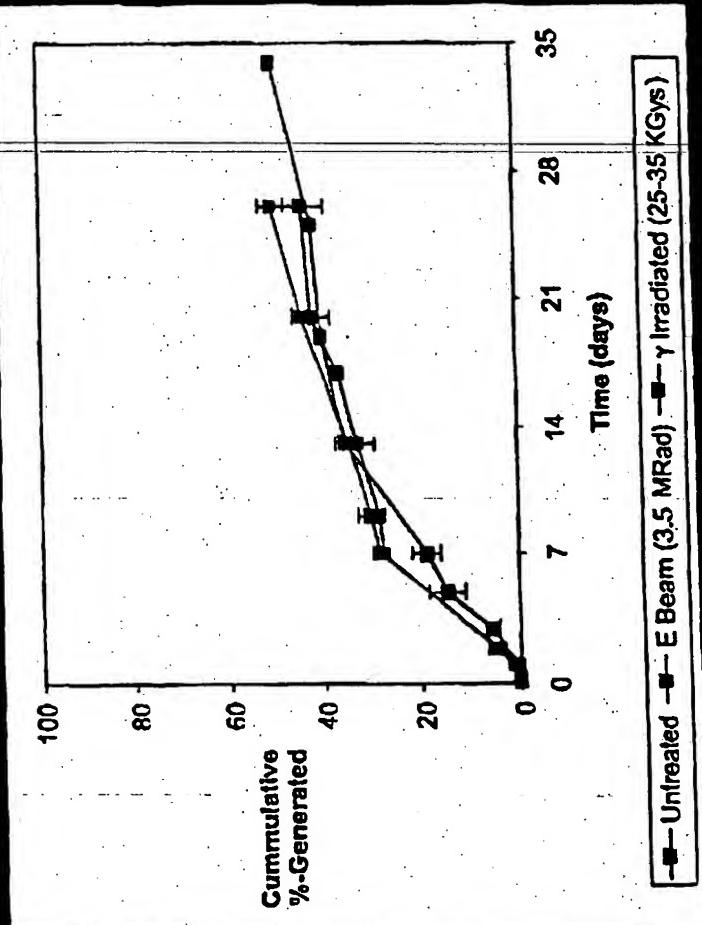
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FIG. 24

Erosion of Sterilized PolyAspirin II

Generation of Diflunisal into 37 °C Serum from
~5 μm -thick Coatings on 316L SS Plates



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FIG. 25

γ Irradiation (25-35 Kgy's)

Property	PolyAspirin I PX261 $M_w \sim 20K$	PolyAspirin II PX657 $M_w \sim 100K$
MW	N/C	-50%
Hardness	-2 units	-3 units
Flexibility	N/C	-
Adhesion	N/C	N/C: no change

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FIG. 26

E Beam (3-4.5 MRad)

PolyAspirin I

PolyAspirin II

Property	PX261 $M_w \sim 20K$	PX657 $M_w \sim 33K$	$M_w \sim 80K$
MW	-26%	+5%	-30%
Hardness	-1 unit	+2 units	N/C
Flexibility	N/C	-	N/C
Adhesion	-1 unit	-	N/C: no change

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FIG. 27

Kinetics of NSAID Generation

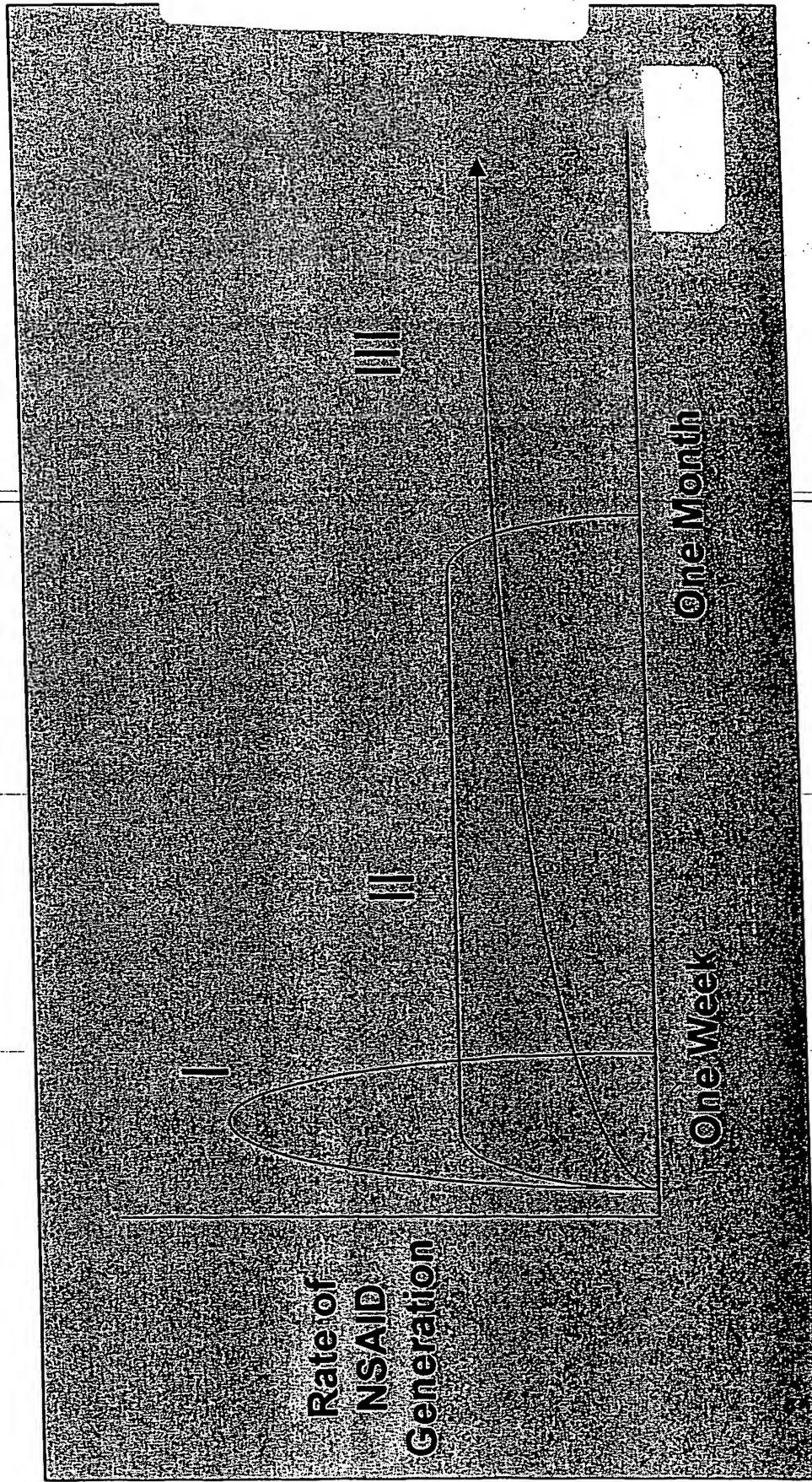


FIG. 28

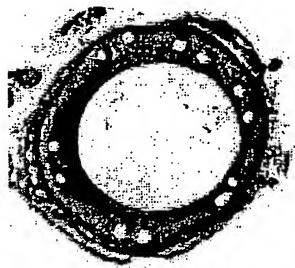


FIG. 29

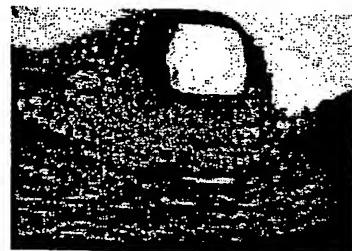
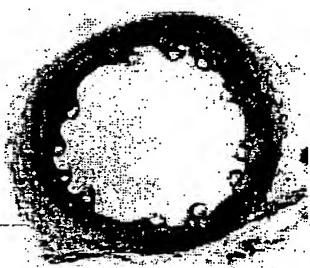


FIG. 30

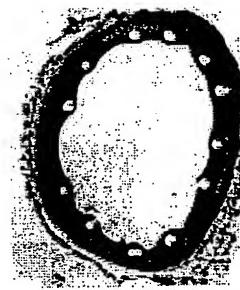


FIG. 31

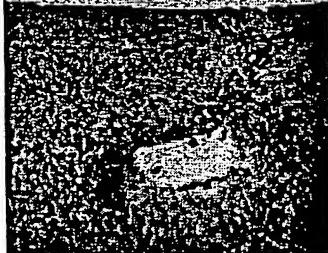
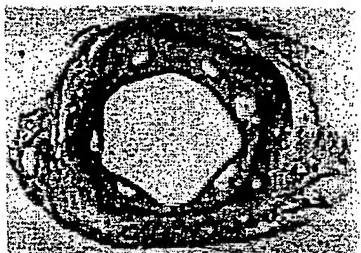


FIG. 32



FIG. 33

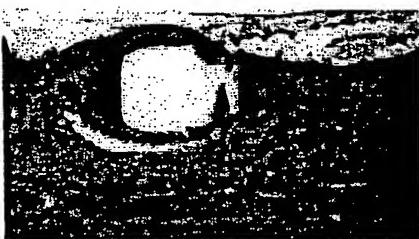
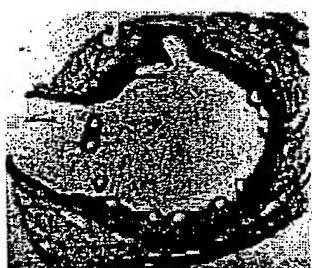


FIG. 34

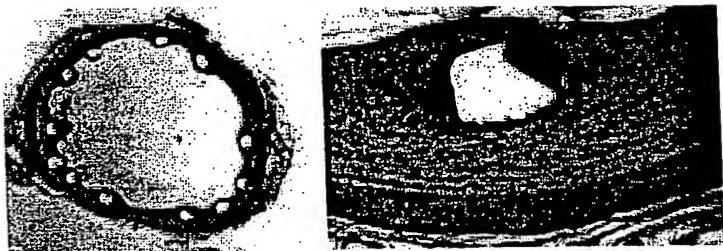


FIG. 35

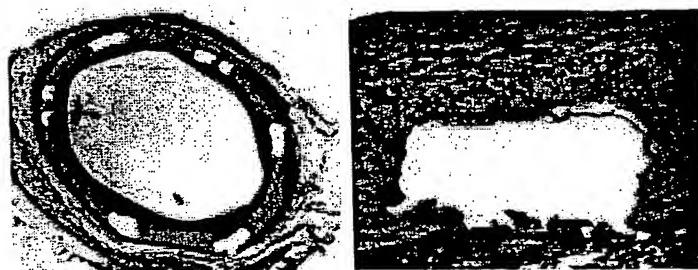


FIG. 36

FIG. 37

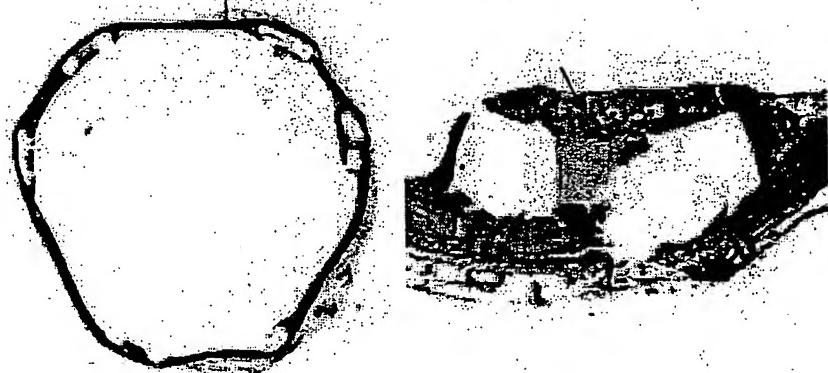


FIG. 38

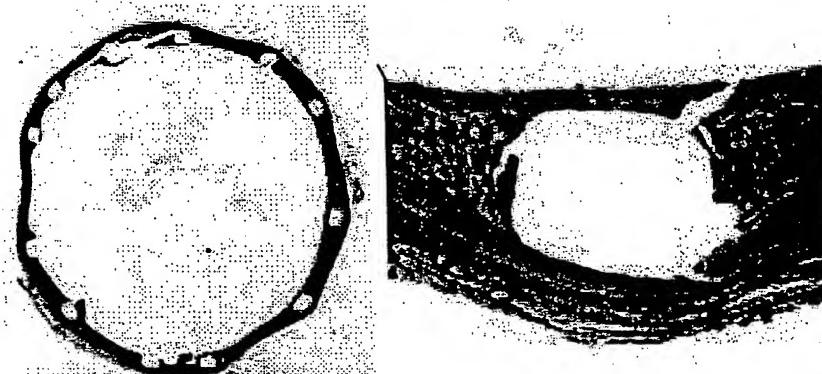
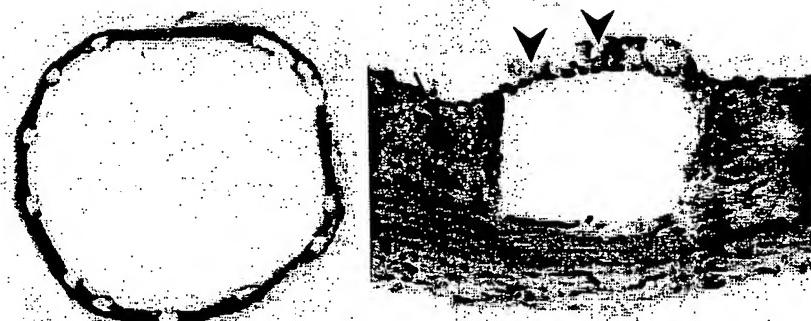


FIG. 39



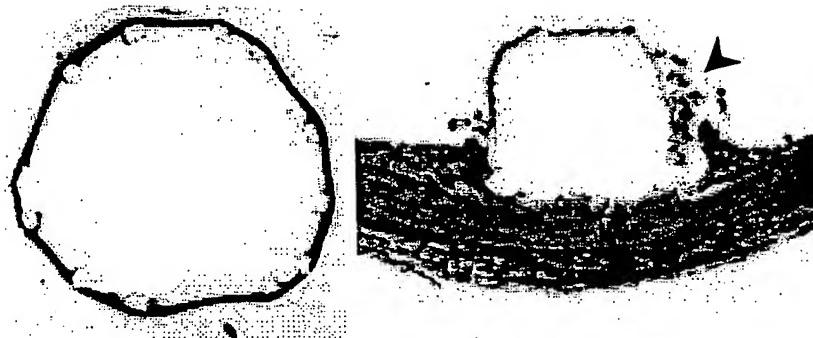


FIG. 40

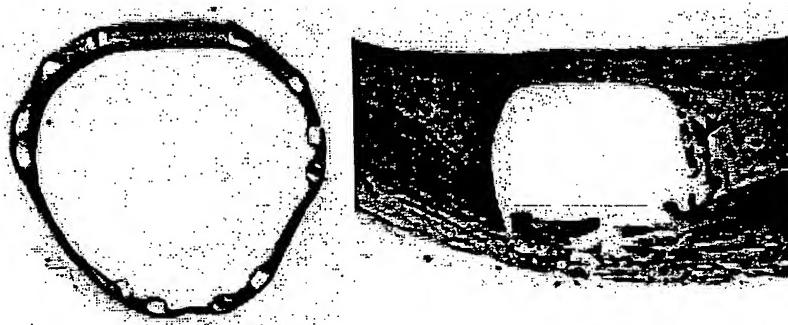


FIG. 41

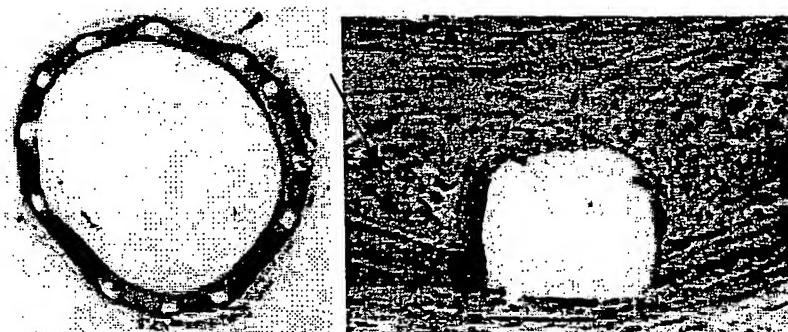


FIG. 42

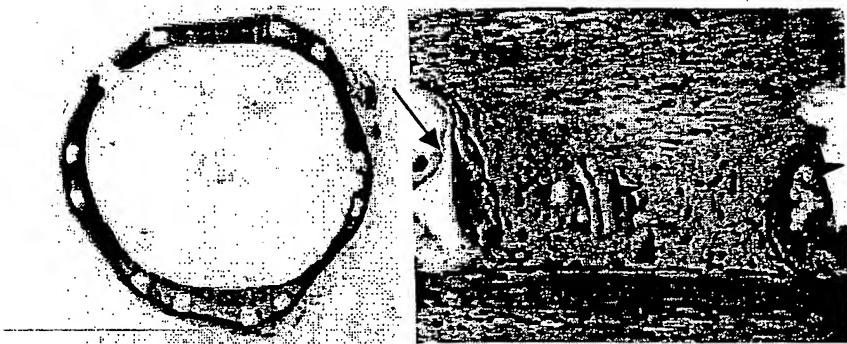


FIG. 43

uncrimped/unexpanded

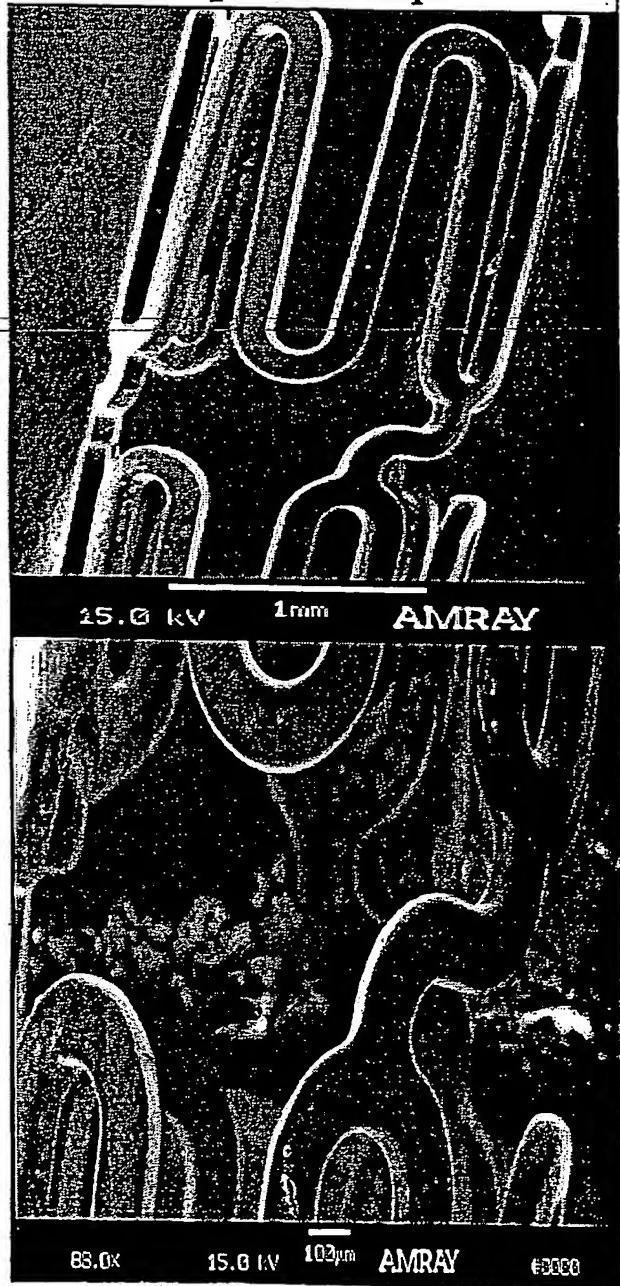


FIG. 44a

FIG. 44b

uncrimped/unexpanded

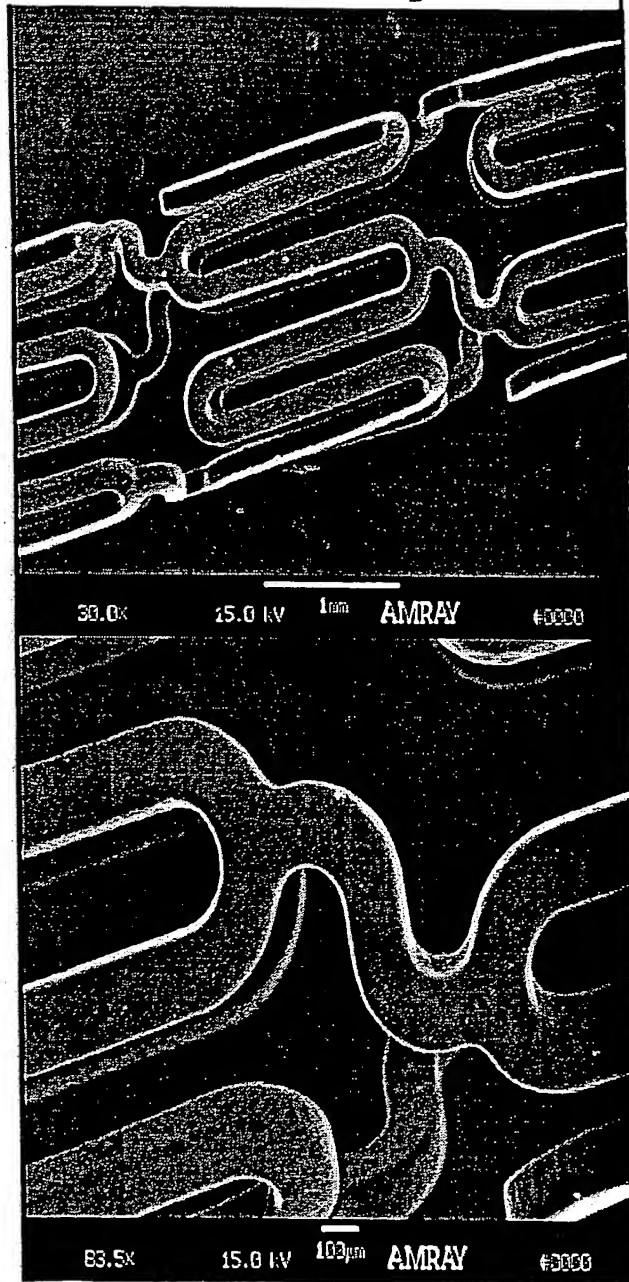


FIG. 45a

FIG. 45b

uncrimped/unexpanded

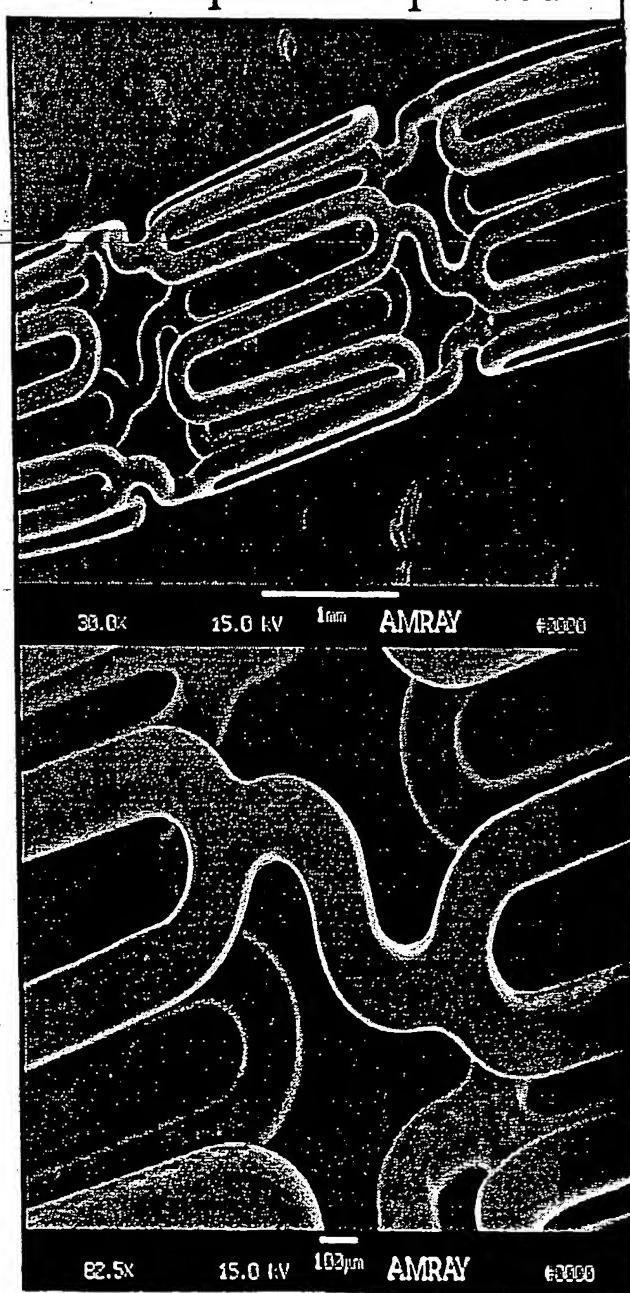


FIG. 46a

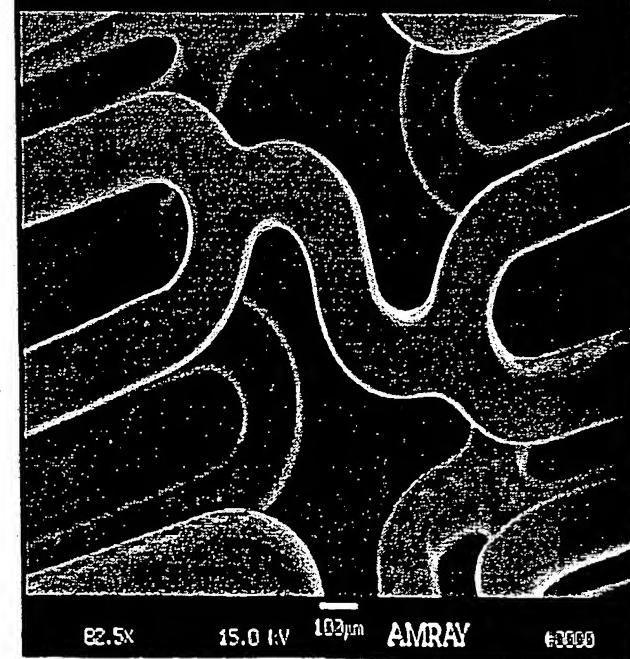


FIG. 46b

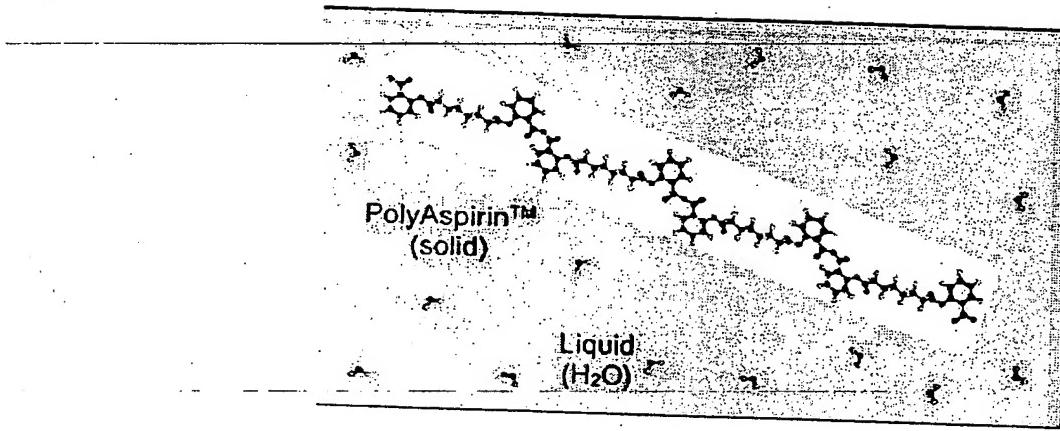


Fig. 47



Fig. 48

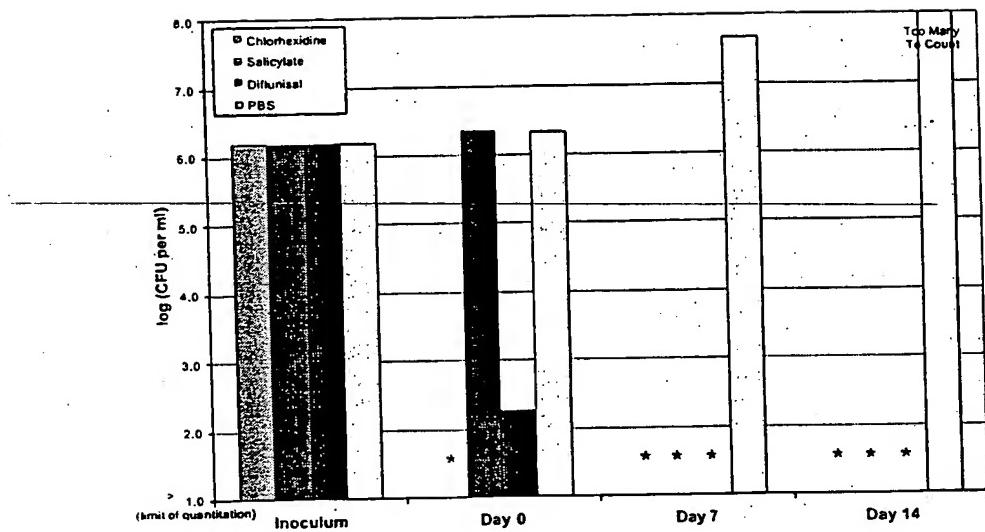


Fig. 49

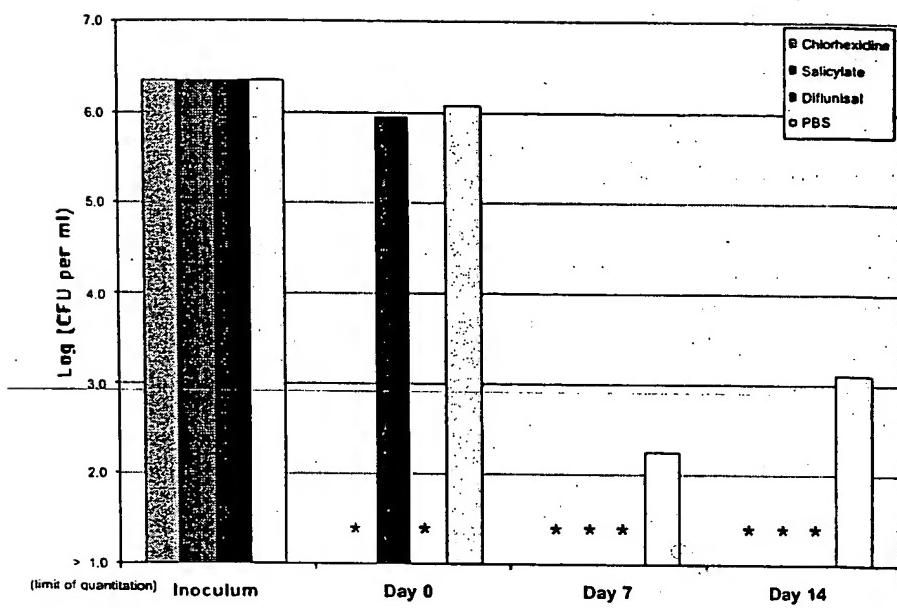


Fig. 50

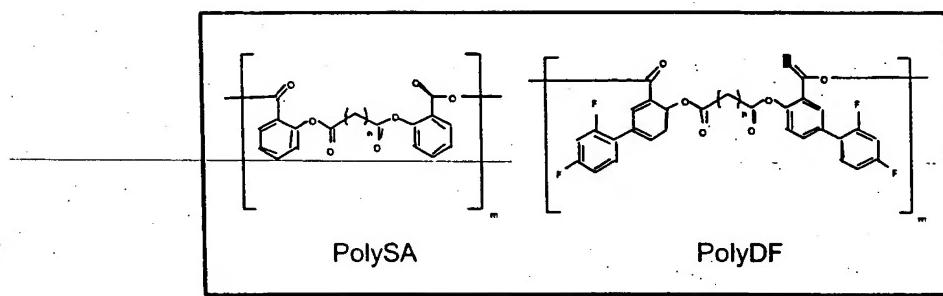


Fig. 51

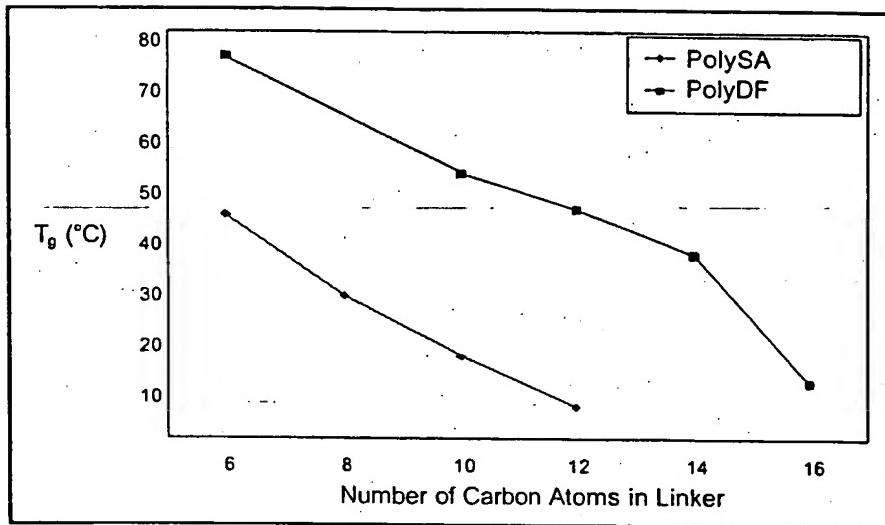


Fig. 52

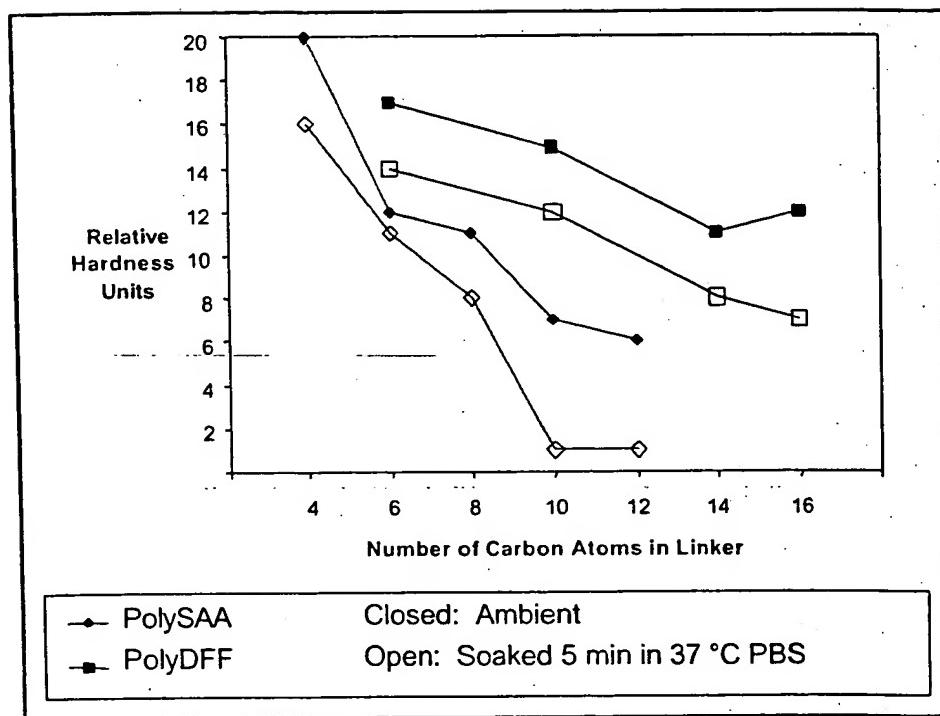
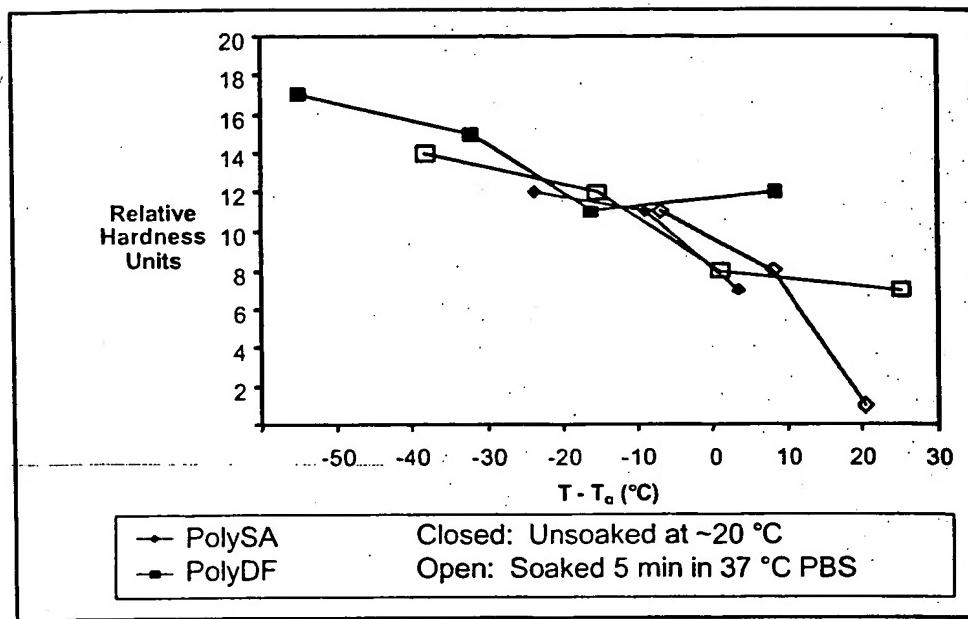


Fig. 53



Frg. 54

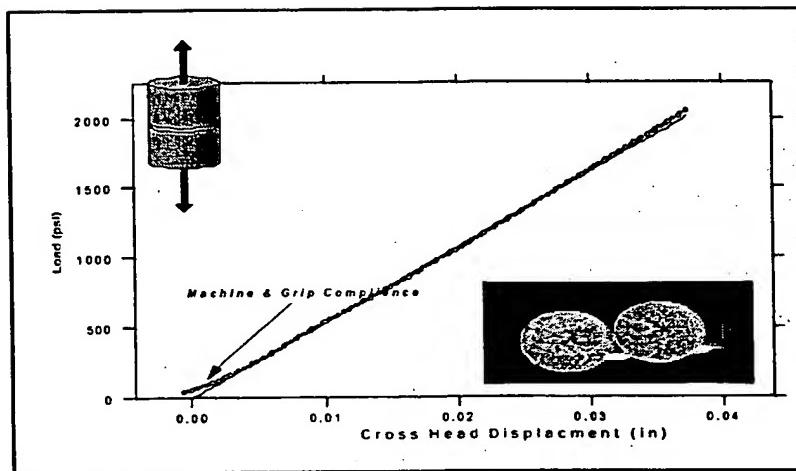


Fig. 55

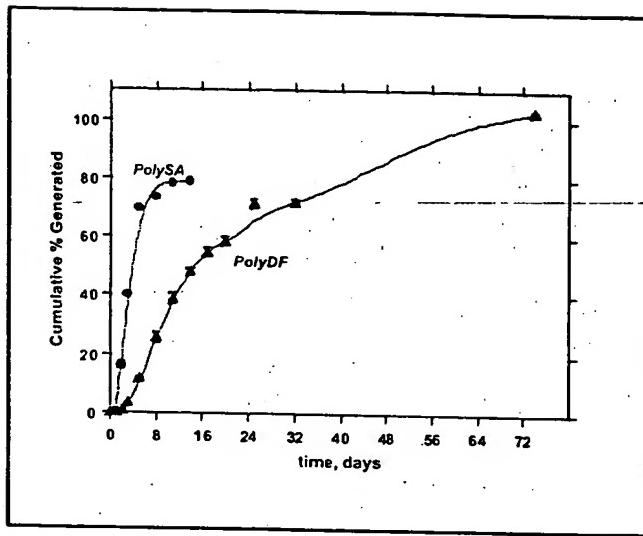


Fig. 56

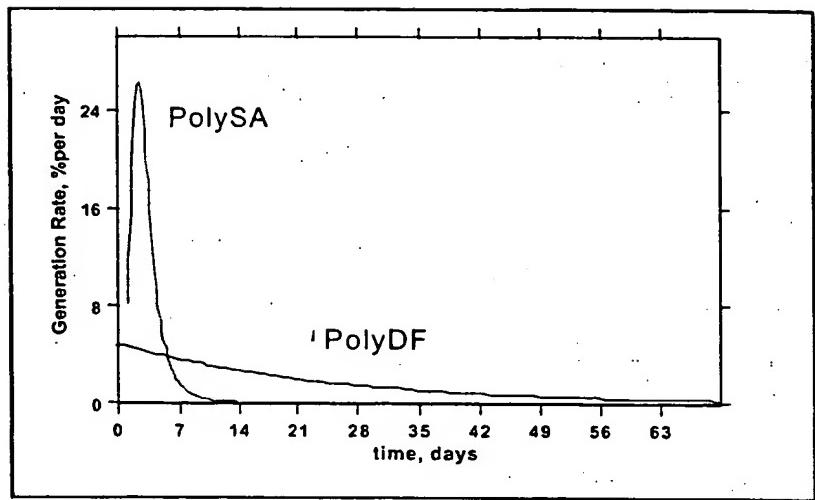


Fig. 57

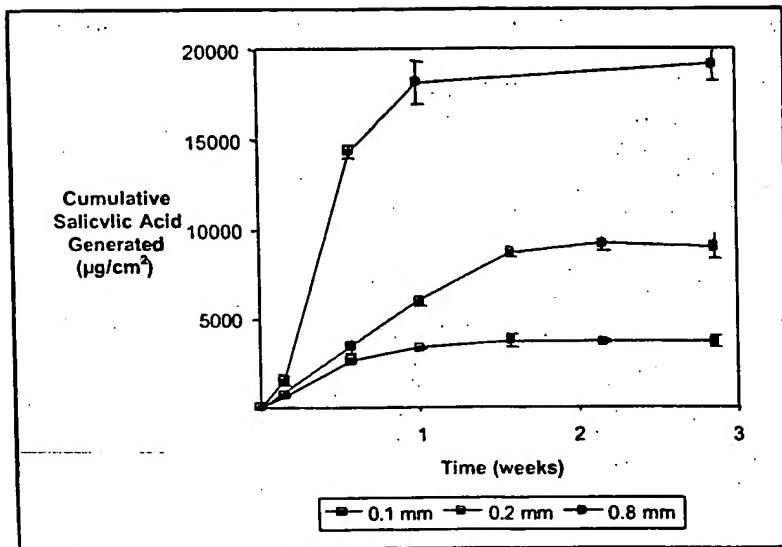


Fig. 58

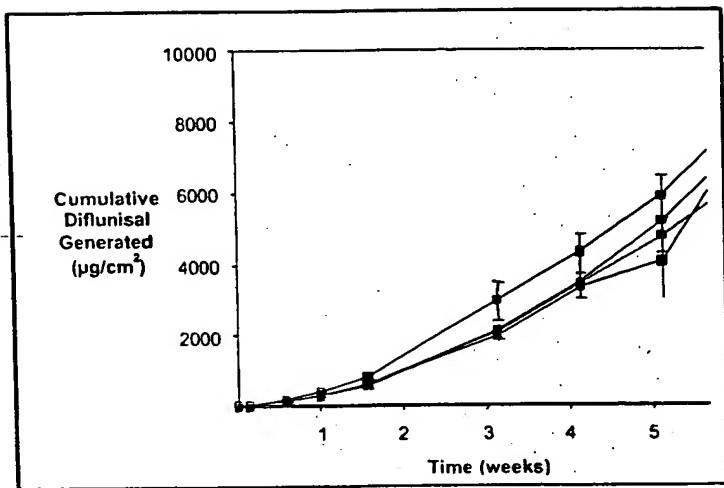


Fig. 59

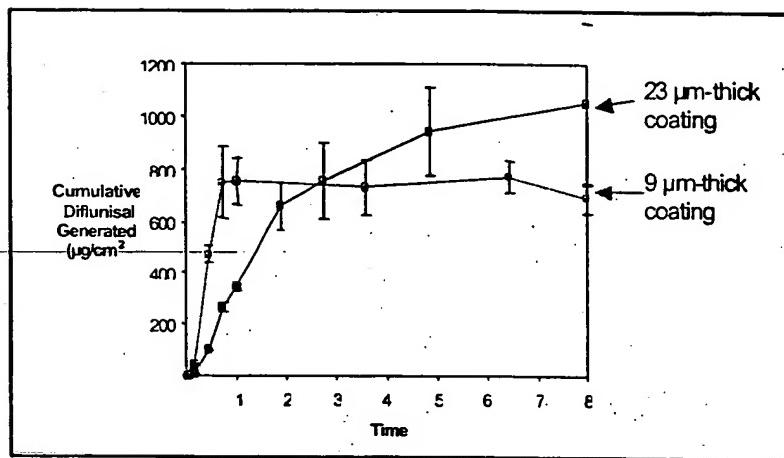


Fig. 60

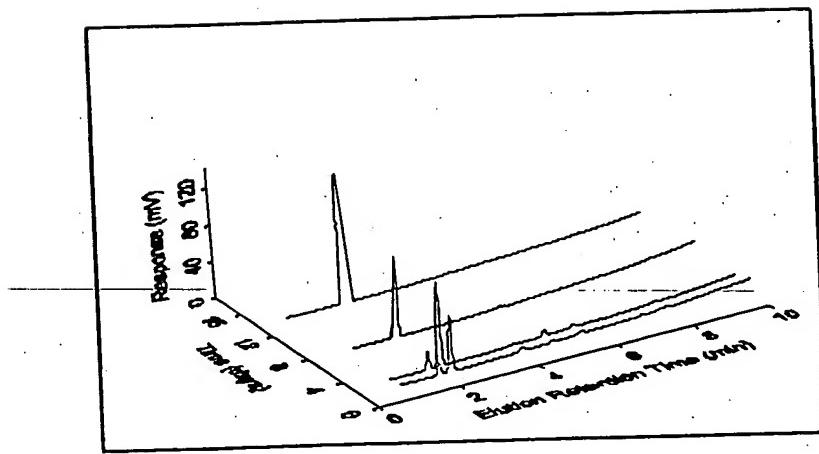


Fig. 61

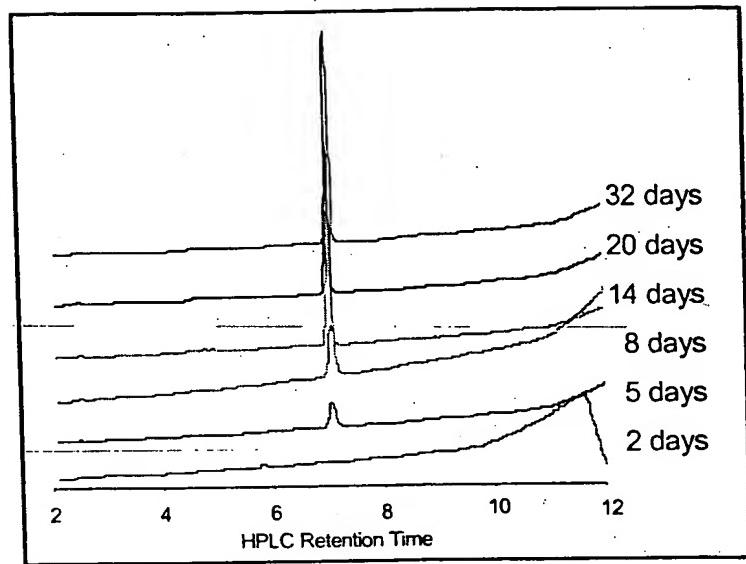


Fig. 62

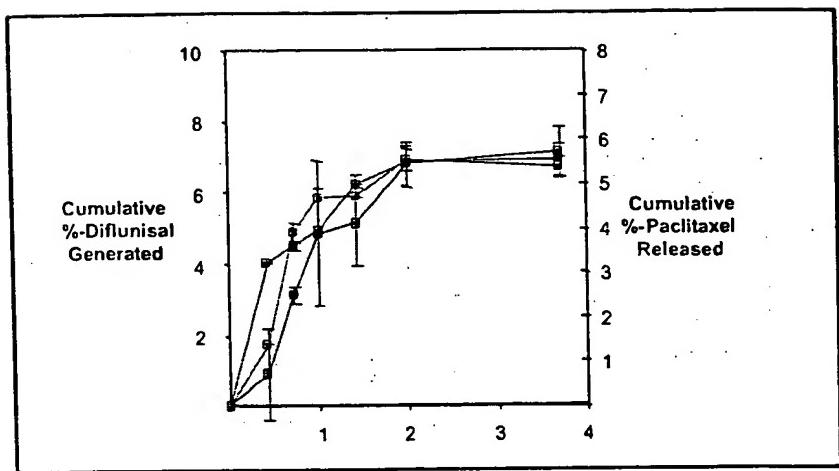


Fig. 63

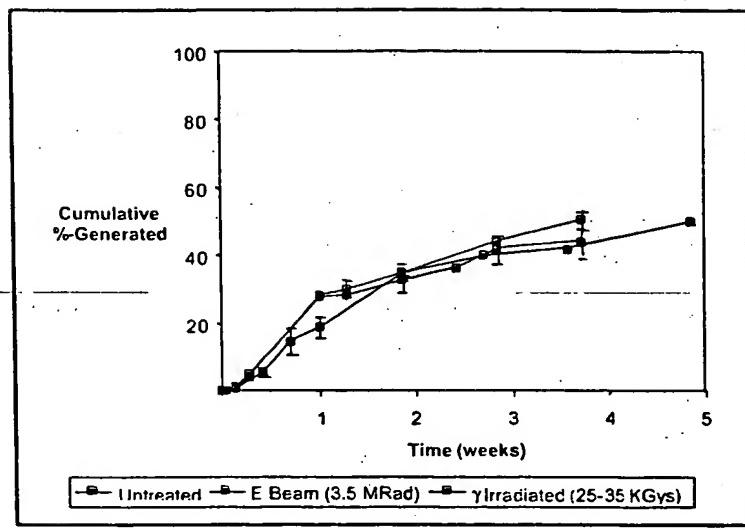


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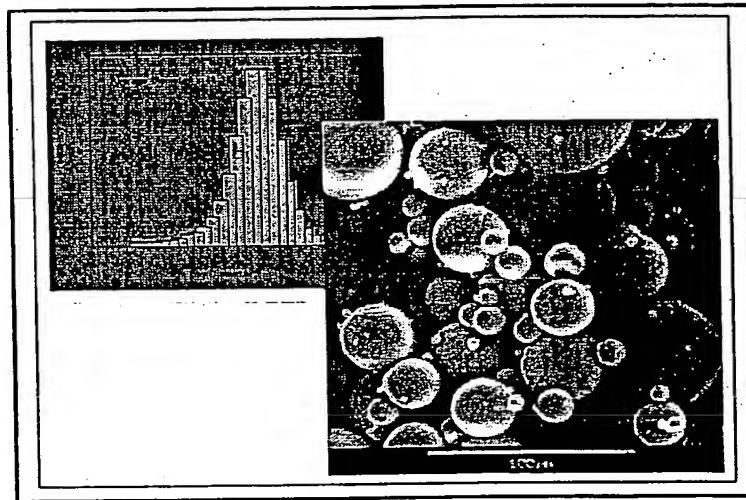


Fig. 65

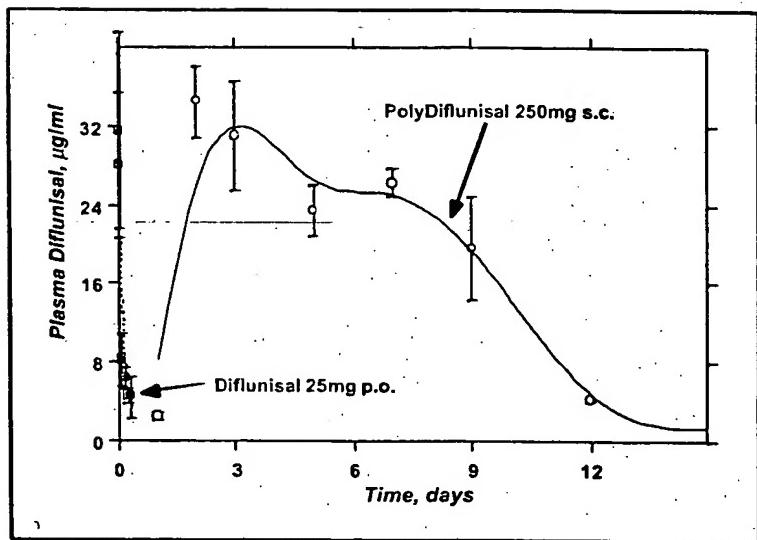


Fig. 66

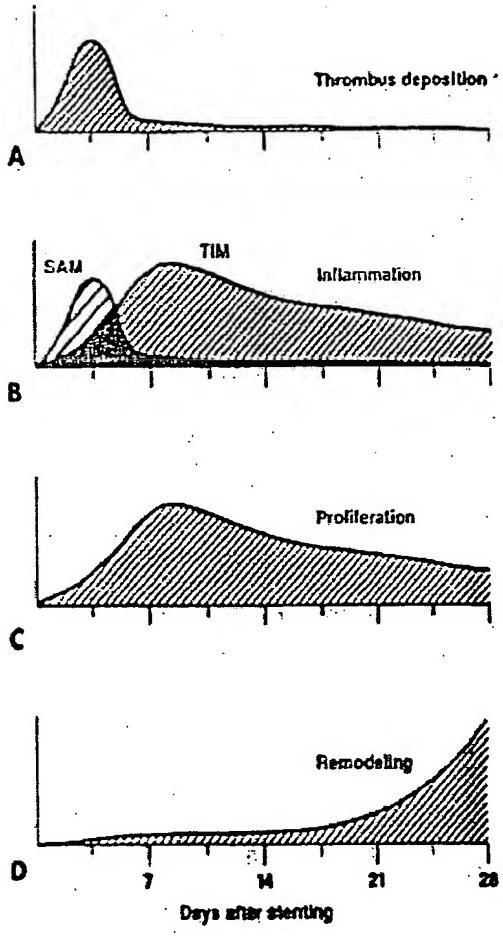


Fig. 67

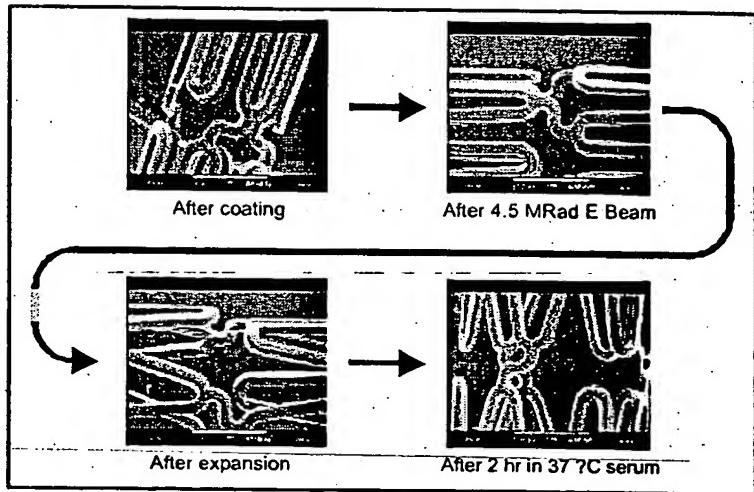


Fig. 68

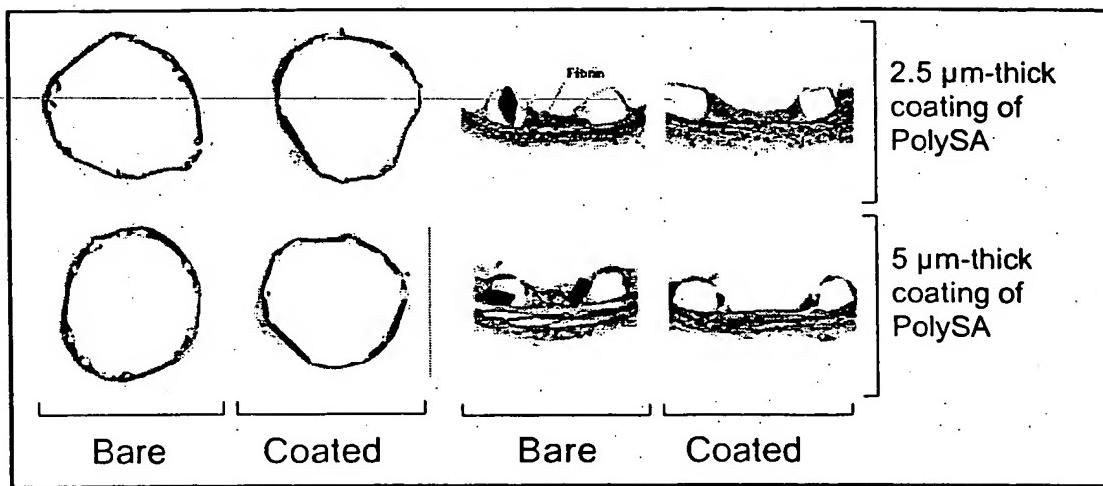


Fig. 69

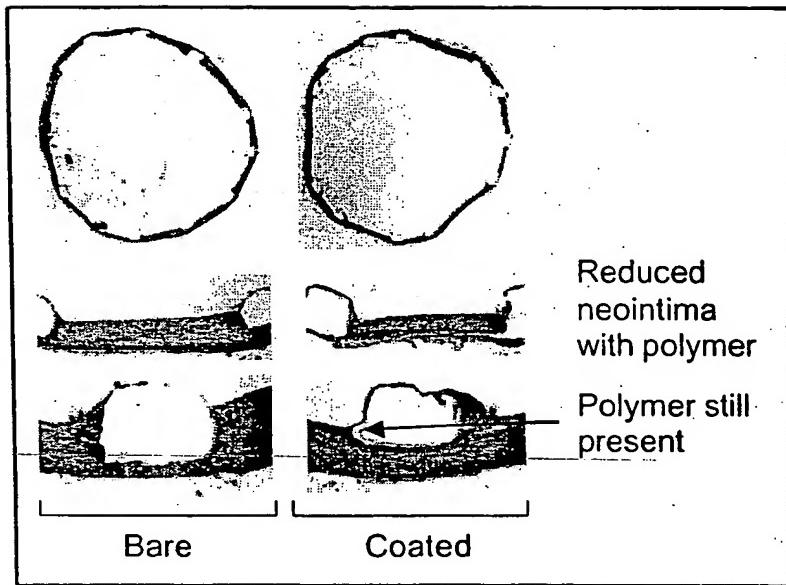


Fig. 70